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Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs

Pier DeRoo
University of Michigan Law School

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STUDENT NOTE

“PUBLIC NON-COMMERCIAL USE” COMPULSORY LICENSING FOR PHARMACEUTICAL DRUGS IN GOVERNMENT HEALTH CARE PROGRAMS

*Pier DeRoo**

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INTRODUCTION

Suppose a relatively prosperous nation with universal public health coverage faces an HIV/AIDS crisis. It refuses to negotiate with the patent-holding manufacturers of the best antiretrovirals (ARVs) available, instead issuing compulsory licenses. Compulsory licenses permit the generic drug manufacturers designated in the compulsory licenses to make, use, import, and sell the patented ARVs without the permission of the patent owners, increasing competition and lowering prices.¹ Realizing that drugs are much cheaper without patents,² the nation decides to issue another round of compulsory licenses for an extensive list of patented drugs for its universal health care program. While improving public access to these drugs, the compulsory licenses also reduce the market exclusivity that patent holders depend on, decreasing the patent holders' anticipated return on their research and development (R&D) investments. Whether governments may legally act in this manner under the current Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has profound consequences for public access to pharmaceuticals and for public and private contributions to pharmaceutical R&D, especially as health care purchasing power continues to consolidate in the hands of government programs.³

1. Broadly defined, a compulsory license may be issued by a government to permit a third party to make, use, or sell patented technology without the permission of the patent holder. A government seeking to increase access to pharmaceutical drugs will usually issue the compulsory license to a state-run pharmaceutical company, or solicit bids from domestic and international generic pharmaceutical producers, resulting in lower prices for the compulsory-licensed drugs than under the patent monopoly. See JEROME H. REICHMANN WITH CATHERINE HASENZAH, *NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS* 10 (Int'l Ctr. for Trade and Sustainable Dev. & United Nations Ctr. for Trade and Dev., Issue Paper No. 5) (defining compulsory licensing); Peggy B. Sherman & Ellwood F. Oakley III, *Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 AM. BUS. L. J. 353, 369 (2004) (defining compulsory licensing); see also COMM'N ON INTELLECTUAL PROP. RIGHTS, *INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY* 42 (2002) [hereinafter CIPR REPORT] (discussing pharmaceutical compulsory licensing); CAROLYN DEERE, *THE IMPLEMENTATION GAME* 229–32 (2009) (describing compulsory licensing negotiations); Jon Cohen, *Brazil, Thailand Override Big Pharma Patents*, 316 SCI. 816, 816 (2007) (describing pharmaceutical compulsory licensing); Editorial, *Theft in Thailand*, WALL ST. J. (Asia ed.), Feb. 10, 2007, at A8 (anticipating that Thailand, despite having a domestic generic drug industry, would turn to India to supply cheaper generic drugs).

2. Thailand, for example, expected its HIV/AIDS compulsory licenses to halve treatment costs. See MINISTRY OF PUB. HEALTH & NAT'L HEALTH SEC. OFFICE, *FACTS AND EVIDENCES ON THE 10 BURNING ISSUES RELATED TO THE GOVERNMENT USE OF PATENTS ON THREE PATENTED ESSENTIAL DRUGS IN THAILAND* 13 (2007) (Thai.) [hereinafter *THAI WHITE PAPER*]; Nicholas Zamiska, *Thai Move to Trim Drug Costs Highlights Growing Patent Rift*, WALL ST. J. (Asia ed.), Jan. 30, 2007, at A8.

3. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S.

The TRIPS Agreement forms one of the three pillars of the World Trade Organization (WTO),⁴ formally linking intellectual property (IP) protection with trade. In order to harmonize IP protection at a global level, TRIPS aims to "reduce distortions and impediments to international trade" from an IP perspective.⁵ Thus, TRIPS obligates all WTO Member states to implement a minimum regime of IP rights to provide security and predictability, and to ensure that IP protection contributes "to the mutual advantage of producers and users of technological knowledge."⁶ For many countries, the minimum TRIPS standards required that they take pharmaceutical drugs out of the public domain.⁷

TRIPS recognizes that patents may pose an inappropriate barrier to technology access under certain circumstances, and therefore permits Member states to use compulsory licenses. Through compulsory licensing and other "TRIPS flexibilities,"⁸ IP harmonization is incomplete.⁹ A

299 [hereinafter TRIPS]. All World Trade Organization (WTO) Members are required to be parties to TRIPS. Marrakesh Agreement Establishing the World Trade Organization art. II.2, Apr. 15, 1994, 1867 U.N.T.S. 154 ("The agreements and associated legal instruments included in Annexes 1, 2 and 3 . . . are integral parts of this Agreement, binding on all Members.").

4. The three pillars of the WTO regime are TRIPS; the Multilateral Agreements on Trade in Goods, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187; and the General Agreement on Trade in Services, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1B, 1869 U.N.T.S. 183.

5. TRIPS pmbl.

6. *Id.* arts. 1.1, 7.

7. *Id.* art. 27.1 ("[P]atents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology."). Although most developing nations inherited colonial intellectual property (IP) laws, certain reformist nations like India, Brazil, and Mexico had lowered patent protection for pharmaceuticals in order to ensure a cheap supply of drugs for their populations. DEERE, *supra* note 1, at 40. They had to increase pharmaceutical patent protection under TRIPS, although they were given a period of time to implement these changes. *Id.* at 68–69, 70–74. One account of the TRIPS negotiations suggests that African nations "signed a death warrant for citizens of their country" by accepting heightened IP protections. PETER DRAHOS WITH JOHN BRAITHWAITE, *INFORMATION FEUDALISM* 142 (2002).

8. "TRIPS flexibilities" are the provisions that explicitly or implicitly permit deviation from the intended harmonizing minimum standards of IP rights. *See* World Trade Organization, Declaration on the TRIPS Agreement and Public Health, ¶¶ 4, 5(b), WT/MIN(01)/DEC/2 (Nov. 14, 2001), 41 I.L.M. 755 (2002) [hereinafter Doha Declaration] ("We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. . . . [W]e reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide *flexibility* for this purpose. . . . [W]e recognize that these *flexibilities* include [compulsory licensing, etc.]" (emphases added).

9. *See* TRIPS art. 31. TRIPS is further flexible, for example, with regard to patentable subject matter, patent exhaustion, and substantive standards for patentability. *See id.* art. 27.3 (permitting member states to exclude medical procedures and life forms from patentability); *id.* art. 6 (leaving the issue of exhaustion of intellectual property rights to member states); *id.* art. 27.1 (requiring only that an invention be "new, involve an inventive step, and [be] capable of industrial application," without dictating the strength of these criteria); Geeta Anand, *Drug Makers Decry Indian Patent Law*, WALL ST. J., Feb. 12, 2010, <http://online.wsj.com/article/SB10001424052748703455804575057621354459804.html> (illustrating that the Indian patent

compulsory license, which must be issued by a government, revokes a patent holder's property right¹⁰ to exclude any party designated in the compulsory license from making, using, importing, or selling the patented invention.¹¹ Pharmaceutical compulsory licenses therefore prevent innovative pharmaceutical producers from suing for infringement the generic manufacturers producing and selling under the compulsory licenses. In these situations, patent-holding producers must compete with generic producers who did not have to incur the significant drug development and regulatory approval costs.¹²

TRIPS therefore restricts the permissible situations for granting compulsory licenses. Under TRIPS Article 31(b), compulsory licenses may be used (1) when reasonable commercial negotiations have failed; (2) without prior negotiation when a national emergency or other circumstance of extreme urgency has arisen; or (3) without prior negotiation when the compulsory license is for "public non-commercial use."¹³ Nearly every compulsory license for pharmaceutical drugs under TRIPS has aimed to increase access to ARVs to combat HIV/AIDS epidemics,¹⁴ which falls squarely within the enumerated "national emergency" language of TRIPS Article 31.¹⁵ In 2006 and 2007, however, Thailand issued three compulsory licenses under the public non-commercial use provision.¹⁶ Two of the compulsory licenses permitted generic production of patented HIV/AIDS drugs; the other permitted

agency "has a higher bar for issuing patents," much to the consternation of the pharmaceutical industry).

10. TRIPS pmbl. ("[r]ecognizing that intellectual property rights are private rights").

11. See sources cited *supra* note 1.

12. See, e.g., Cohen, *supra* note 1, at 816 (describing Merck's competition with a generic version of an HIV/AIDS drug under compulsory license); Editorial, *Drugs in Thailand*, FIN. TIMES (London), Jan. 31, 2007, at 14 (describing a generic version of an HIV drug under compulsory license, which undercut Merck's market for its patented version); Jean Francois Tremblay, *Drug Patent Struggles in Asia*, CHEMICAL & ENGINEERING NEWS, Feb. 5, 2007, at 11 (describing legal activity taken by innovative pharmaceutical companies faced with generic competition under compulsory licenses); see also DEERE, *supra* note 1, at 230–32 (illustrating that the mere threat of a compulsory license often causes patent-holding pharmaceutical companies to reduce prices).

13. TRIPS art. 31(b); see also DEERE, *supra* note 1, at 81–82 (noting that a compulsory license can only be granted after reasonable negotiations have failed, although "[prior negotiation] does not apply in the case of public, non-commercial use or in the case of a national emergency"); Cynthia Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS*, 34 N.C. J. INT'L L. & COM. REG. 371, 400 (2009) (describing three situations when prior negotiation is not required: "a national emergency, a 'circumstance of extreme urgency,' or public non-commercial use").

14. Countries issuing compulsory licenses have included Mozambique, Swaziland, Malaysia, Zambia, Zimbabwe, India, Guinea, Ghana, Rwanda, Brazil, and Thailand. See DEERE, *supra* note 1, at 229–30.

15. See Doha Declaration, *supra* note 8, ¶ 5(c) ("it being understood that public health crises, including those relating to HIV/AIDS . . . can represent a national emergency").

16. See THAI WHITE PAPER, *supra* note 2, at 38–46.

generic production of Plavix, a heart disease drug.¹⁷ In 2008, Thailand issued compulsory licenses for four anti-cancer drugs, also under the public non-commercial use provision.¹⁸

No WTO panel decision has defined "public non-commercial use," but pharmaceutical compulsory licenses issued by government health care programs appear to fall within the public non-commercial use restriction. Because a government issuing a compulsory license usually distributes the generically produced drugs to its citizens through its health care program, the use appears public.¹⁹ Furthermore, because the government program will generally provide the drugs to the public free of charge or on a non-profit basis, the use also appears non-commercial.²⁰ Indeed, legal scholars generally agree that any definition of public non-commercial use encompasses "government use" of the patented technology.²¹ A few scholars have even suggested that the vagueness of public non-commercial use may permit nearly limitless

17. *Id.*

18. MINISTRY OF PUB. HEALTH & NAT'L HEALTH SEC. OFFICE, THE 10 BURNING QUESTIONS REGARDING THE GOVERNMENT USE OF PATENTS ON THE FOUR ANTI-CANCER DRUGS IN THAILAND 22–29 (2008) (Thai.). The Thai government cancelled one of the compulsory licenses after one patent holder agreed to provide its cancer drug for free, but after a governmental regime change, the new government indicated it would not revoke its other three anti-cancer compulsory licenses. Ho, *supra* note 13, at 415–19; Darren Schuettler, *Thailand Scraps Patent Override on Novartis Drug*, REUTERS ALERTNET, Feb. 1, 2008, <http://www.alertnet.org/thenews/newsdesk/BKK24285.htm> [hereinafter Schuettler, *Thailand Scraps Patent Override*]; Nopporn Wong-Anan, *Thailand Will Override Cancer Drug Patents*, REUTERS, Mar. 10, 2008, available at <http://www.reuters.com/article/idUSBKK14764720080310>; see also Sinfah Tunsarawuth, *Thailand Avoids Compulsory License on Cancer Drug; 3 More Drugs Undecided*, INTELLECTUAL PROPERTY WATCH (Jan. 31, 2008), <http://www.ip-watch.org/weblog/2008/01/31/thailand-avoids-compulsory-licence-on-cancer-drug-3-more-drugs-undecided/>.

19. See, e.g., E. Richard Gold & Danial K. Lam, *Balancing Trade in Patents: Public Non-Commercial Use and Compulsory Licensing*, 6 J. WORLD INTELL. PROP. 5, 25 (2003); Ho, *supra* note 13, at 402–04.

20. See Gold & Lam, *supra* note 19, at 25–26; Ho, *supra* note 13, at 412–13. A governmental single-payer health care program is the paradigmatic example of a purely government-run health care program. This governmental character gradually deteriorates the more patients have to pay out of pocket for treatment. See, e.g., CONSTITUTION OF THE KINGDOM OF THAIL., § 51 (2007) ("A person has the right to be appropriately protected by the State against harmful contagious diseases, and to have such diseases eradicated, without charge and in a timely manner.").

21. MICHAEL BLAKENEY, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS* 91 (1996) ("[Public non-commercial use] will invariably be use by government or by a government instrumentality."); CARLOS M. CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS* 316 (2007) (substituting the term "government use" for public non-commercial use); Gold & Lam, *supra* note 19, at 25; see Ho, *supra* note 13, at 431–32; Patrick Marc, *Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?*, 21 N.Y.L. SCH. J. INT'L & COMP. L. 109, 116 (2001); Jerome H. Reichmann, Comment, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 256 (2009).

justification for compulsory licensing.²² By utilizing “public non-commercial use” compulsory licensing for arguably non-emergency medicines addressing non-infectious diseases like heart disease and cancer,²³ Thailand has begun to illustrate the possibility of employing compulsory licensing purely as a cost-control element of a government health care program.²⁴ Such extensive compulsory licensing by government health care programs raises serious concerns for governments, patients, taxpayers, and the pharmaceutical industry. These concerns include governments’ abilities to fulfill universal health care promises, disproportionate burden-sharing for publicly funded R&D among developed nations, potential disincentives for pharmaceutical companies to research financially risky areas of medicine, and the continued viability of TRIPS if it contains significant pharmaceutical loopholes.

In light of the multifaceted challenge that compulsory licensing represents in an era of government-run health care, this Note sidesteps

22. James Love, *Access to Medicine and Compliance with the WTO TRIPS Accord: Models for State Practice in Developing Countries*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS 74, 74 (Peter Drahos & Ruth Mayne eds., 2002) (“[TRIPS] is actually fairly permissive on [compulsory licensing]. For example, for public non-commercial use, . . . the only obligation [is] the payment of ‘adequate’ compensation.”); SISULE F. MUSUNGU & CECILIA OH, COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? 20 (2005) [hereinafter CIPIH REPORT]; Gold & Lam, *supra* note 19, at 25–26, 30 (arguing that public non-commercial use should be similarly “liberally interpreted”); Ho, *supra* note 13, at 402–04 (coming to a definition “sufficiently broad to cover nearly any use relating to a nation’s citizens . . . [not] for business or profit”).

23. For example, one commentator described the Plavix licensing efforts as “challeng[ing] patents for a ‘life-style’ disease,” although there are no minimum criteria for determining whether a disease has reached national emergency status. Piya Wong, *Thailand Backs Off Threat to Break Drug Patents*, SCIDEV.NET (Feb. 8, 2007), <http://www.scidev.net/en/news/thailand-backs-off-threat-to-break-drug-patents.html>; see also Roger Bate, *Thai-ing Pharma Down*, WALL ST. J. (Eastern ed.), Feb. 9, 2007, available at <http://www.aei.org/article/25585> (“[P]atents can be broken in emergencies. However, it’s hard for anyone to argue that heart disease meets such stringent tests.”); *Bangkok’s Drug War Goes Global*, WALL ST. J., Mar. 7, 2007, <http://online.wsj.com/article/SB117322181443628799.html> (“Thailand clearly doesn’t have an HIV/AIDS epidemic, and heart disease isn’t a ‘national emergency.’”); *Theft in Thailand*, *supra* note 1.

24. This Note recognizes that categorizing diseases as “emergencies” or “non-emergencies” or “lifestyle diseases” is a tenuous endeavor, since HIV/AIDS could be framed, for example, as the result of the unfortunate lifestyle choice to engage in unprotected sexual activity. Accordingly, given Thailand’s compulsory licenses under the public non-commercial use provision of TRIPS Article 31(b), and its maintenance of a “wish list” of patented drugs to treat cancer and other diseases, this Note instead suggests that Thailand has at least contemplated a broad program of compulsory licensing under the public non-commercial use provision, and attempts to address the issues that broader similar compulsory licensing practices present. See THAI WHITE PAPER, *supra* note 2, at 2 (noting that Thai citizens are entitled to full access to 900 drugs, many patented, on the government’s essential drugs list); Editorial, *The Licensing of Key Drugs*, BANGKOK POST, June 16, 2010, <http://www.bangkokpost.com/opinion/opinion/38827/the-licensing-of-key-drugs> (illustrating that Thailand continues to maintain its compulsory licensing practices).

other drastic reform proposals,²⁵ pragmatically attempting to discern limits on "public non-commercial use" within the current TRIPS regime of patent rights. Part I reviews the evolution of compulsory licensing practices under TRIPS. Part II presents the new compulsory licensing concerns raised by the growth of government-run health care, taking into account health care's status as a human right, the economic realities of pharmaceutical R&D, and recent shifts in the global pharmaceutical market. Part III analyzes the TRIPS context in which the public non-commercial use restriction appears, while Part IV interprets public non-commercial use and finds that TRIPS establishes an appropriate balance for public non-commercial use. Part V concludes.

I. THE EMERGENCE OF COMPULSORY LICENSING UNDER TRIPS

Throughout the Uruguay Round negotiations, which spawned the WTO and TRIPS, the United States advocated a compulsory licensing provision narrowly limited to declared national emergencies, national

25. Many have suggested alternative remedies to ensure expanded access to pharmaceutical drugs while maintaining the profit margins required for continued research and development (R&D). Some of these include adjusting the TRIPS-mandated royalty payments to the patent holder under a compulsory license, employing parallel importation to encourage price competition, segregating markets to better enable price discrimination, and governmental R&D systems. See, e.g., Daniel R. Cahoy, *Confronting Myths and Myopia on the Road from Doha*, 42 GA. L. REV. 131 (2007); Patricia M. Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, 3 INT'L J. HEALTH CARE FIN. ECON. 183 (2003); John A. Harrelson, *TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 WIDENER L. SYMP. J. 175 (2001); Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil*, 6 YALE HUM. RTS. & DEV. L.J. 103, 111–12 (2003); Antony Taubman, *Rethinking TRIPS: 'Adequate Remuneration' for Non-Voluntary Patent Licensing*, 11 J. INT'L ECON. L. 927 (2008).

Policy changes tend to occur at a glacial pace at the politically charged intersection of patents and public health. See, e.g., Frederick M. Abbott & Jerome H. Reichmann, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 933 (2007) (pessimistically expressing, with regard to the TRIPS Amendment, WTO General Council, *Amendment of the TRIPS Agreement, Decision of 6 December 2005*, WT/LJ/641 (Dec. 8, 2005), that "[t]he authors are inclined to believe there is not much room in the present global political environment for negotiating a different deal from the one presently on the table"); *In Parenthesis*, ECONOMIST, Nov. 13, 1999, at 112 (describing that in WTO trade-liberalization talks "[t]here are 77 paragraphs and they're nearly all bracketed. That means almost nothing is agreed" . . . Many developing countries, including India and Pakistan, say they will not even discuss an agenda for further liberalization unless they are granted some leeway in implementing previous commitments in such areas as intellectual property and customs practices. But America, among others, says this is tantamount to reopening done deals. And so on.").

security, and critical peril to the life of the general public.²⁶ Powerful developing countries, first pushing to keep IP issues outside the Uruguay negotiations, later advocated for a broader compulsory licensing provision.²⁷ The final agreement represented a compromise, permitting Member countries to issue compulsory licenses on their individual merits (1) when reasonable commercial negotiations have failed; (2) without prior negotiation when a national emergency or other circumstance of extreme urgency has arisen; or (3) without prior negotiation when the compulsory license is for "public non-commercial use."²⁸ No relevant WTO panel decisions or other authoritative interpretations of this language exist, leaving countries facing health problems hopeful that compulsory licensing will help improve access to drugs, while the pharmaceutical industry fears that extensive compulsory licensing will dissolve its R&D structure and leave a generic drug commodities market in its place.²⁹ Compulsory licensing practices, however, continue to expand from responding to purely national emergencies toward addressing everyday health care.

A. National Emergency Compulsory Licensing

Compulsory licensing for epidemics constituting national emergencies has grudgingly gained acceptance. Initially, compulsory licensing addressing HIV/AIDS and other epidemics was successfully deterred³⁰

26. DRAHOS WITH BRAITHWAITE, *supra* note 7, at 145; DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 3, 248 (2d ed. 2003) (providing the July 23, 1990 draft text of TRIPS Article 31).

27. Certain developing countries, especially India and Brazil, attempted to negotiate compulsory licensing provisions as broadly as possible. *See* DEERE, *supra* note 1, at 54–56; REICHMANN WITH HASENZAH, *supra* note 1, at 14; Reichmann, *supra* note 21, at 247–48 ("[I]f the developing countries lost the war, in the sense that their generic pharmaceutical industries could no longer freely reverse-engineer [foreign patented drugs], then they won a great battle with specific regard to the question of compulsory licenses.").

28. TRIPS art. 31(b); DEERE, *supra* note 1, at 81–82; *see also* Ho, *supra* note 13, at 399–400.

29. A commodities market for pharmaceuticals merely reflects the costs of ingredients and production, leaving little margin to conduct R&D. For a brief discussion of a knowledge-based R&D industry encountering a market-shift to a commodities market, *see* DRAHOS WITH BRAITHWAITE, *supra* note 7, at 57–60.

30. Developing countries hoped that the multilateral TRIPS Agreement would reduce or eliminate bilateral trade pressure to strengthen IP protection. *See, e.g.,* DEERE, *supra* note 1, at 159; MICHAEL P. RYAN, *KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY* 112 (1998). The United States in particular, however, has actually increased its use of bilateral trade pressure post-TRIPS, although actual retaliation has been rare. *See* DEERE, *supra* note 1, at 159–61, 341–42. Europe has also been active, although at times a "quiet free-rider" on American bilateral trade activity. *Id.* at 50; *see, e.g.,* DRAHOS WITH BRAITHWAITE, *supra* note 7, at 7. Although some maintain that the "whole point of multilateral agreements is to protect countries from the bilateral jungle where the strongest always win," a WTO panel has upheld U.S. bilateral trade legislation in a case brought by the

by U.S. "sticks and carrots" trade legislation in the form of benefits under the Generalized System of Preferences³¹ (GSP), Section 301,³² and the Special 301 "watch lists."³³ IP-related trade pressure came to a cataclysmic convergence with public health interests in South Africa in the late 1990s, however, when the South African government issued compulsory licenses for drugs to combat its rapidly spreading HIV/AIDS epidemic.³⁴

Nelson Mandela signed amendments to South Africa's Medicines and Related Substances Control Act³⁵ in late 1997 to allow South Africa to buy cheaper drugs from other countries via parallel importation³⁶ to

European Union. Evelyne Herfkens, Comment, *TRIPs and Public Health, Opportunities for Doha*, BRIDGES (Int'l Ctr. for Trade & Sustainable Dev.), Oct. 2001, at 3, 3, available at <http://ictsd.org/downloads/bridges/bridges5-8.pdf>; Panel Report, *United States—Sections 301–310 of the Trade Act of 1974*, ¶¶ 1.1, 8.1, WT/DS152/R (Dec. 22, 1999).

31. 19 U.S.C. §§ 2461–2467 (2006); see DRAHOS WITH BRAITHWAITE, *supra* note 7, at 86. The Generalized System of Preferences (GSP) program is "designed to promote economic growth in the developing world [by] provid[ing] preferential duty-free treatment for over 3,400 products from 131 designated beneficiary countries and territories." OFFICE OF THE U.S. TRADE REPRESENTATIVE, U.S. GENERALIZED SYSTEM OF PREFERENCES (GSP) GUIDEBOOK 3 (2010). Because developing countries depend on trade with the United States more than the reverse, threatening revocation of GSP benefits is an effective method of encouraging strong IP protection. See DRAHOS WITH BRAITHWAITE, *supra* note 7, at 86–88.

32. 19 U.S.C. § 2411 (2010) (permitting, and sometimes requiring, that the United States Trade Representative take appropriate action if "an act, policy, or practice of a foreign country is unreasonable or discriminatory and burdens or restricts United States commerce," including inadequate or ineffective protection of IP rights).

33. 19 U.S.C. § 2242 (2010) (requiring that the United States Trade Representative (USTR) formulate lists of countries that deny adequate and effective protection of intellectual property rights, with those having the most egregious acts or policies going on the priority watch list). The USTR thereby publishes, in increasing order of severity, a "watch list," a "priority watch list," and a list of "priority foreign countries." Priority foreign countries have been said to reside on "trade's death row." Peter Drahos, *Global Law Reform and Rent-Seeking: The Case of Intellectual Property*, 7 AUSTL. J. CORP. L. 45, 51 (1996). There are, however, political limits to bilateral trade pressure. India, for example, has made itself a permanent fixture either as a priority foreign country or on the priority watch list for eighteen consecutive years without suffering trade sanctions. See DRAHOS WITH BRAITHWAITE, *supra* note 7, at 88 (noting that India last suffered GSP trade sanctions in 1992); *The U.S. Special 301 Reports, 1989 to 2010*, KNOWLEDGE ECOLOGY INT'L, <http://keionline.org/ustr/special301> (last visited Nov. 13, 2010).

34. See Kathy Chenault et al., *Will the AIDS Plague Change U.S. Trade Policy?*, BUS. WK., Sept. 13, 1999, at 58 (noting that around sixteen percent of South African adults are HIV-positive).

35. Medicines and Related Substances Control Amendment Act No. 90 of 1997 (S. Afr.).

36. Parallel importation occurs when a country with high drug prices purchases from a source in a country with lower drug prices. On an individual consumer level, if a pharmaceutical company charges a high price to U.S. consumers, some U.S. consumers might seek to purchase their drugs from another country where prices are lower, such as Canada, thereby engaging in parallel importation. See Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3 CHI. J. INT'L L. 47, 63 (2002); see also Mary Pat Flaherty & Gilbert M. Gaul, *Millions of Americans Look Outside U.S. For Drugs: Desire for Low*

ensure availability of essential medicines, which appeared illegal under TRIPS.³⁷ Treating this as a test run to enforce TRIPS restrictions on compulsory licensing, developed countries and the pharmaceutical industry mobilized remarkably: in February 1998, thirty-nine pharmaceutical companies filed a lawsuit against the South African government; in May, the United States Trade Representative (USTR) put South Africa on the Special 301 Watch List; in June, GSP benefits were held in abeyance on items for which South Africa had requested GSP treatment; and in October, U.S. Congress cut off aid to South Africa pending a State Department report detailing South Africa's efforts to repeal the law.³⁸

South Africa made no substantive changes in its law and weathered the full brunt of U.S., European, and industry pressure until the tide began to turn in 1999 as public scrutiny escalated.³⁹ The *Chicago Tribune* described it as a "battle pit[ting] the drug firms . . . against the intentions

Prices Often Outweighs Obeying Law, WASH. POST, Oct. 23, 2003, <http://www.washingtonpost.com/wp-dyn/content/article/2007/06/28/AR2007062801634.html>. Parallel importation has importance beyond pricing when a country issues a compulsory license, but does not have a domestic pharmaceutical industry capable of producing the drugs under license. See, e.g., World Health Organization (WHO), *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, at 19–21, WHO/EDM/PAR/2002.3, 34 (June 2002) (by Carlos M. Correa) [hereinafter *Implications of the Doha Declaration*]. TRIPS was amended in 2005 to explicitly permit parallel importation under such a situation. WTO General Council, *Amendment of the TRIPS Agreement*, WT/L/641 (Dec. 8, 2005).

37. TRIPS requires that production under a compulsory license be "predominantly for the supply of the domestic market." TRIPS art. 31(f). Thus, a country producing under a compulsory license will likely have very little excess supply to import to other countries having a compulsory license on the same drug without treading into uncertain legal territory. After a recent TRIPS amendment, however, parallel importation is permitted in situations like the one South Africa faced in the late 1990s. See *infra* text accompanying notes 50–52.

38. DEERE, *supra* note 1, at 227–28; [1 MAKING THE RULES] CHARAN DEVEREAUX ET AL., CASE STUDIES IN US TRADE NEGOTIATION 82–87 (2006); Marc, *supra* note 21, at 121–22; Chenault et al., *supra* note 34, at 58; Pharm. Research Mfrs. Ass'n, Submission of the Pharmaceutical Research and Manufacturers of America (PhRMA) for the National Trade Estimate Report on Foreign Trade Barriers (NTE) 2000: South Africa (Dec. 3, 1999) (unpublished report), available at <http://www.cptech.org/ip/health/phrma/nte-99/safrica.html>; see Act of Oct. 21, 1998, Pub. L. No. 105-277, 112 Stat. 2681-1, 2681-155 ("[N]one of the funds appropriated under this heading may be made available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports . . . on the steps being taken . . . to negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997[.]"). The USTR also alleged in its Special 301 Report that "[d]uring the past year, South African representatives have led a faction of nations in the World Health Organization (WHO) in calling for a reduction in the level of protection provided for pharmaceuticals in TRIPS." 1999 USTR SPECIAL 301 REP. 21.

39. See Marc, *supra* note 21, at 117, 119–22.

of some countries to issue [compulsory licenses]."⁴⁰ The *New York Times* later criticized the U.S. government, stating:

[The dispute] has revealed the need to broaden the Administration's policy, which has been dominated by trade issues and the desire to protect American pharmaceutical patents. Washington should stop pressuring South Africa to change the law, but even then far more will need to be done to get lifesaving medicines to poor Africans with AIDS.⁴¹

By October, reports covered protestors' chants of "Gore's Greed Kills" in response to "the way the Clinton/Gore Administration has been using political and economic blackmail to keep Third World countries from [issuing compulsory licenses for or parallel importing] patented AIDS-fighting drugs, many of which were developed with [U.S.] taxpayer-funded research."⁴²

The publicity nightmare quickly penetrated Washington, D.C.⁴³ In September 1999, the USTR reached a settlement permitting South Africa to use the compulsory licensing provisions of TRIPS to enhance access to pharmaceutical drugs, while South Africa pledged to "honour its obligations under the TRIPS Agreement."⁴⁴ In May 2000, President Clinton signed an Executive Order prohibiting the U.S. government from taking Section 301 action against sub-Saharan African countries whose laws promote access to HIV/AIDS pharmaceuticals and comply with TRIPS.⁴⁵ The pharmaceutical industry held out until 2001, but ultimately reached a similar agreement whereby the pharmaceutical industry withdrew its lawsuit and South Africa promised to apply the compulsory licensing laws with discretion.⁴⁶

40. Merrill Goozner, *Third World Battles for Aids Drugs*, CHI. TRIB., Apr. 28, 1999, http://articles.chicagotribune.com/1999-04-28/news/9904280067_1_compulsory-licensing-south-africa-aids-drugs; see also DEERE, *supra* note 1, at 229.

41. Editorial, *Drugs for AIDS in Africa*, N.Y. TIMES, Aug. 23, 1999, <http://www.nytimes.com/1999/08/23/opinions/drugs-for-aids-in-africa.html?scp=2&sq=%22drugs+for+aids+in+africa%22&st=nyt>.

42. Doug Ireland, Editorial, *AIDS Drugs for Africa*, NATION, Oct. 4, 1999, at 5.

43. See, e.g., *id.*

44. Press Release, S. Afr. Dep't of Trade & Indus., Joint Understanding Between the Governments of South Africa and the United States of America (Sept. 17, 1999), available at <http://www.info.gov.za/speeches/1999/9909201219p1007.htm>; DEVEREAUX ET AL., *supra* note 38, at 87; Steven Lee Myers, *South Africa and U.S. End Dispute over Drugs*, N.Y. TIMES, Sept. 18, 1999, at A8.

45. Exec. Order No. 13155, 3 C.F.R. 268, 270 (2000).

46. The parties essentially agreed that South Africa would proceed "cautiously and prudently" with regards to compulsory licensing practices. DEERE, *supra* note 1, at 229. The pharmaceutical industry also lowered the prices of HIV/AIDS medications in Africa while "requiring assurances that the drugs would not be reexported elsewhere and demonstration of an adequate health care infrastructure." DEVEREAUX ET AL., *supra* note 38, at 90-91, 94.

The South Africa confrontation permanently altered the TRIPS flexibilities landscape. In its 2001 WTO dispute with Brazil, the U.S. withdrew from a potential WTO panel decision, unwilling to “give credence to the idea of the WTO interfering with poor countries’ health policies.”⁴⁷ Emboldened, developing countries pursued a multilateral declaration of their right to use TRIPS flexibilities, “not because of the lack of clarity in [TRIPS], but as a result of the obstacles that the authorities in those countries had experienced when trying to make effective use of such flexibility.”⁴⁸ The resulting Doha Declaration on the TRIPS Agreement and Public Health at the WTO Doha Ministerial Conference in November 2001 affirmed:

that [TRIPS] can and should be interpreted and implemented in a manner supportive of WTO Members’ rights to protect public health and, in particular, to promote access to medicines for all.

In this connection, we affirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.⁴⁹

The Doha Agreement recognizes that “[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licences are granted,”⁵⁰ and that “HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”⁵¹ Because many developing nations lack the domestic pharmaceutical manufacturing facilities necessary to produce a drug after a compulsory license, a TRIPS Amendment was passed in 2005, which permits countries to use parallel importation “to the extent necessary for the purposes of production of a pharmaceutical product(s).”⁵²

After the Doha Agreement, compulsory licensing began to proliferate to address national emergencies or other circumstances of extreme urgency. Between 2002 and 2005, Brazil, Eritrea, Ghana, Indonesia, Malaysia, Mozambique, Zambia, and Zimbabwe issued compulsory licenses

47. *US, Brazil End WTO Case on Patents, Split on Bilateral Process*, INSIDE U.S. TRADE, June 29, 2001, at 1, 2.

48. *Implications of the Doha Declaration*, *supra* note 36, at 2.

49. Doha Declaration, *supra* note 8, ¶ 4.

50. *Id.* ¶ 5(b).

51. *Id.* ¶ 5(c).

52. *Amendment of the TRIPS Agreement*, *supra* note 36, art. 31bis, ¶ 1; Press Release, WTO, Members OK Amendment to Make Health Flexibility Permanent (Dec. 6, 2005), available at http://www.wto.org/english/news_e/pres05_e/pr426_e.htm; see also Taubman, *supra* note 25, at 935 (noting that this TRIPS Amendment “remains the sole formal amendment to the entire Uruguay Round package”).

for generic HIV/AIDS drugs.⁵³ Threats of compulsory licensing in negotiations have also successfully reduced prices for drugs to combat HIV/AIDS⁵⁴ and Asian influenza.⁵⁵ Even the United States has recognized compulsory licensing as a useful bargaining chip in negotiating a steep discount on Cipro in response to the 2001 anthrax scare.⁵⁶ Despite gradually gaining acceptance, however, compulsory licensing practices remained confined to addressing national emergencies until the most recent compulsory licenses issued between 2006 and 2008.

B. The Emergence of Public Non-Commercial Use Compulsory Licensing

Thailand, after the September 19, 2006 military coup, radically departed from the generally accepted "national emergency" compulsory licensing for HIV/AIDS drugs.⁵⁷ On November 29, 2006, Thailand's military-appointed leaders of the Department of Disease Control issued a compulsory license for an HIV/AIDS drug, Efavirenz;⁵⁸ on January 24, 2007, they issued a compulsory license for another HIV/AIDS drug, Kaletra;⁵⁹ and on January 25, 2007, they issued a compulsory license for the heart disease medication Plavix.⁶⁰ All were granted under the "public non-commercial use" provision.⁶¹ Claiming that "I am not a politician

53. See Reichman, *supra* note 21, at 250; *Examples of Health-Related Compulsory Licensing*, CONSUMER PROJECT ON TECH., <http://www.cptech.org/ip/health/cl/recent-examples.html> (last visited Nov. 13, 2010).

54. See, e.g., Zamiska, *supra* note 2; Keith Alcorn, *Brazil Wins 75% Discount on New HIV Drug*, AIDSMAP NEWS (Nov. 17, 2003), <http://www.aidsmap.com/en/news/5719B079-1568-4614-89D7-C51F8A3DC6A1.asp>.

55. See Reichman, *supra* note 21, at 249–50.

56. *Id.* at 250; Jill Carroll & Ron Winslow, *Bayer Agrees to Slash Price for Cipro Drug*, WALL ST. J., Oct. 25, 2001, at A3.

57. Karen Emmons et al., *One Night in Bangkok: Army Claims Coup in Thailand*, INDEPENDENT, Sept. 20, 2006, at 1.

58. Notification of the Department of Disease Control, Ministry of Public Health Re: Exercising of Right Under Drugs and Pharmaceuticals Products Patent (Nov. 29, 2006) (Thai.), in THAI WHITE PAPER, *supra* note 2, at 38–40 [hereinafter Thai Efavirenz License]; see also Apiradee Treerutkuarkul, *Local Version of New AIDS Drug Planned*, BANGKOK POST, Nov. 29, 2006.

59. Notification of the Department of Disease Control, Ministry of Public Health Re: Exercising of Right Under Drugs and Pharmaceuticals Products Patent for Combined Formulation of Lopinavir and Ritonavir (Jan. 24, 2007) (Thai.), in THAI WHITE PAPER, *supra* note 2, at 41–43 [hereinafter Thai Kaletra License].

60. Notification of the Department of Disease Control, Ministry of Public Health Re: Exercising of Right Under Drugs and Pharmaceuticals Products Patent for Clopidogrel (Jan. 25, 2007) (Thai.), in THAI WHITE PAPER, *supra* note 2, at 44–46 [hereinafter Thai Plavix License].

61. THAI WHITE PAPER, *supra* note 2, at 5–7 (referring to the Thai compulsory licenses as "Government Use of Patent"); Thai Efavirenz License, *supra* note 58; Thai Kaletra License, *supra* note 59; Thai Plavix License, *supra* note 60.

and I have nothing to lose," Thailand's health minister, Dr. Mongkol, further stated that Thailand was considering issuing compulsory licenses for eleven other medicines to fight HIV/AIDS, cancer, and heart disease.⁶²

While health activists applauded Thailand's actions as "a brave decision,"⁶³ the USTR elevated Thailand to the Special 301 Priority Watch List, citing the compulsory licenses as "further indications of a weakening respect for patents."⁶⁴ One pharmaceutical manufacturer retaliated by withdrawing six drug applications for Thai regulatory approval, with a spokesman elaborating: "[t]he Thai government said it will not buy it, so why is there a need for us to register it?"⁶⁵

Surprisingly, the novel concerns raised by the Thai compulsory licenses were lost on many of those representing international trade interests, as they analyzed the licenses under the national emergency justification that Thailand circumvented.⁶⁶ The Wall Street Journal reported that "patents can be broken in emergencies[;] [h]owever, it's hard for anyone to argue that heart disease meets such stringent tests."⁶⁷ It later implied that Thailand's military-installed government had "unilaterally declare[d] an emergency" to suspend patents.⁶⁸ Another Wall Street Journal editorial later lambasted Thailand for breaching at least the spirit, if not the letter of TRIPS because "it's hard to argue that Thailand has an

Thailand issued all three compulsory licenses pursuant to Section 51 of the Thai Patent Act, which governs use for "any service for public consumption or which is of vital importance . . . to prevent or to relieve a severe shortage of food, drugs or other consumption items." Patent Act B.E. 2522, § 51 (1979), *amended by* Patent Act (No.3) B.E. 2542 (1999) (Thai.), *reprinted in* THAI WHITE PAPER, *supra* note 2, at 30. The Thai government maintains that drugs produced under a compulsory license "will be distributed only to those patients who are covered by the government. Those who are well off and can afford to pay out of their own pocket . . . still have to pay the high price of patented products." THAI WHITE PAPER, *supra* note 2, at 6 (emphasis omitted).

62. James Hookway & Nicholas Zamiska, *Harsh Medicine: Thai Showdown Spotlights Threat to Drug Patents: Abbott Protests Move to Buy Copycat Pills, But It Yields on Price*, WALL ST. J., Apr. 24, 2007, at A1; Darren Schuettler, *Interview—Thailand Fed Up with High Drug Prices*, REUTERS, Feb. 18, 2007, available at <http://www.reuters.com/article/idUSSP34188520070219>; *see also* Zamiska, *supra* note 2 (noting that there "are more products for which the government may allow copycat versions").

63. Zamiska, *supra* note 2 (quoting a Doctors Without Borders campaigner); *see also* Nopporn Wong-Anan, *Thailand Issues More Compulsory Drugs Licences*, REUTERS, Jan. 25, 2007, available at <http://www.reuters.com/article/idUSSP13566> ("AIDS activists applauded Bangkok for taking a bold stance").

64. 2007 USTR SPECIAL 301 REP. 27.

65. Cohen, *supra* note 1, at 816; *see* Hookway & Zamiska, *supra* note 62.

66. *See, e.g.*, Kristina M. Lybecker & Elisabeth Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules*, 37 J.L. MED. & ETHICS 222, 233 (focusing on "the debate surrounding what constitutes a 'national emergency,'" rather than public non-commercial use).

67. Bate, *supra* note 23.

68. Zamiska, *supra* note 2.

AIDS epidemic, when its incidence is a little over 1%—and countries such as South Africa are well over 20%. The same goes for heart disease.”⁶⁹

Thailand, however, issued its compulsory licenses for public non-commercial use.⁷⁰ Explaining that Thailand had committed to providing universal health care for most of its population,⁷¹ Dr. Mongkol reasoned that “[w]e have to provide health services to forty-nine million people and with limited resources.”⁷² Although stating valid health justifications for these licenses,⁷³ the Thai government’s compulsory license notifications also explicitly depended on budgetary considerations.⁷⁴ Dr. Mongkol explained, “[i]f they reduce their drug price to our satisfaction, there is no need to make a compulsory license.”⁷⁵ Although the Thai government asserted that it had segregated the market to provide

69. *Theft in Thailand*, *supra* note 1; *see also* Tremblay, *supra* note 12, at 11 (noting Doctors Without Borders’ estimate that 1.5% of Thailand’s population has AIDS).

70. THAI WHITE PAPER, *supra* note 2, at 5–7 (referring to the Thai compulsory licenses as a “Government Use of Patent”); Thai Efavirenz License, *supra* note 58; Thai Kaletra License, *supra* note 59; Thai Plavix License, *supra* note 60.

71. National Health Security Act B.E. 2545 (2002) (Thai.); *see also* *Drugs in Thailand*, *supra* note 12 (noting that Thailand “has committed to free universal healthcare, and faces a particular challenge in treating a large number of HIV-positive patients with drugs that are costly even for far richer countries,” while disapproving of the Plavix compulsory license); Hookway & Zamiska, *supra* note 62 (“Thailand began inching towards its confrontation with the pharmaceutical industry in 2004, when it pledged to provide free AIDS medicine to everyone who needed it.”).

72. Shuettler, *supra* note 62.

73. THAI WHITE PAPER, *supra* note 2, at 13–14 (detailing the individual merits of each compulsory license); Thai Efavirenz License, *supra* note 58; Thai Kaletra License, *supra* note 59; Thai Plavix License, *supra* note 60.

74. Thai Efavirenz License, *supra* note 58, at 39 (“The price of Efavirenz in Thailand is twice the price of the same drug which is generic drug in India. Budget allocated by the government is therefore sufficient to provide only some patients with Efavirenz, while the rest has to use non-patent drugs with higher level of side-effect than Efavirenz because of their lower prices . . . [T]he Thai law on patent empowers the Ministry, Sub-Ministry and Department to exercise the right under any patent without prior authorization of the patent holders *so as to provide public service as mentioned above*.” (emphasis added)); Thai Kaletra License, *supra* note 59, at 42 (“The price of [Kaletra] is currently a lot higher than the price of the same drug which is generic drug in some countries. Therefore, many patients who are resistant to basic formulations of HIV antiretroviral drugs are unable to access to this drug, leading to opportunistic infections and death. Hence, being able to domestically produce or to import HIV antiretroviral drugs with the same generic name into Thailand to replace the original one will lead to the price reduction and the increase in accessibility for patients.”); Thai Plavix License, *supra* note 60, at 45 (“[S]ince the high price and limited budget, 20 percent of patients covered under Universal Coverage scheme can access [Plavix]. As a result of provision of market competition by imported or locally produced generics, price will reduce dramatically and accessibility will increase 6 to 12 times which will conform to the Universal Coverage policy.”).

75. Shuettler, *supra* note 62.

compulsorily licensed drugs only to those who cannot afford them,⁷⁶ distrust runs high.⁷⁷ Indeed, Thailand issued four more compulsory licenses in 2008, this time for anti-cancer drugs for public non-commercial use.⁷⁸ As an alert Wall Street Journal editorial aptly wondered: “[TRIPS] Article 31 provides for compulsory licensing in case of ‘national emergency’ or for ‘public non-commercial use’ . . . Bangkok claims the latter case, which is hard to rebut. What does ‘public non-commercial use’ mean, anyway?”⁷⁹ Considering the lack of clarity surrounding the Thai compulsory licenses and the public non-commercial use standard, Thailand may have provided a preview to how countries can potentially use compulsory licenses to ensure the highest possible quality of care at the lowest possible price in everyday circumstances.

II. NEW COMPULSORY LICENSING CONCERNS PRESENTED BY GOVERNMENT-RUN HEALTH CARE

The idea of a human right to health care and the implementation of comprehensive government health care programs have proliferated across the globe. Governments and their patients, however, are not the only parties concerned with drug prices and availability. The private pharmaceutical industry depends on patent protection, particularly in high-income European countries and the United States, to recoup high R&D costs and fund future development. Taxpayers also contribute billions of dollars in funding for basic research to support pharmaceutical R&D through public research entities, with U.S. funding for its National Institutes of Health (NIH) far outpacing the public R&D funding of all other countries combined. With Europe instituting hard-ceiling health care budgets for its universal health care programs, and with the United States gradually confronting its own health care costs, the large pockets

76. See THAI WHITE PAPER, *supra* note 2, at 6 (“[T]he drugs derived from the Government Use of Patent in Thailand will be distributed only to those patients who are covered by the government. Those who are well off and can afford to pay out of their own pocket . . . still have to pay the high price of patented products.”).

77. See, e.g., 2009 USTR SPECIAL 301 REP. 21 (Thailand remains on the Priority Watch List); *Theft in Thailand*, *supra* note 1; Zamiska, *supra* note 2; Ed Silverman, *Should the US Invade Thailand?*, PHARMALOT (Apr. 26, 2007, 10:32 AM), http://www.pharmalot.com/2007/04/should_the_us_invade_thailand/.

78. MINISTRY OF PUB. HEALTH & NAT’L HEALTH SEC. OFFICE, *supra* note 18, at 22–29; Schuettler, *Thailand Scraps Patent Override*, *supra* note 18; Wong-Anan, *supra* note 18. The Thai government, however, has not invoked one of the compulsory licenses after Novartis agreed to distribute its drug, Glivec, for free to nearly all Thai patients. Reghu Balakrishnan, *Novartis Wins Thai Battle, Setback for Indian Firms*, THE FINANCIAL EXPRESS, <http://www.financialexpress.com/news/novartis-wins-thai-battle-setback-for-indian-firms/268596/>; Schuettler, *Thailand Scraps Patent Override*, *supra* note 18.

79. Bangkok’s Drug War Goes Global, *supra* note 23.

paying for pharmaceutical drugs may be beginning to shrink. Meanwhile, developing countries continue to drive an increasing share of pharmaceutical market growth. With compulsory licensing practices posing both an increasingly attractive option to constrain costs in developed nations and an effective remedy to increase drug access in developing nations, compulsory licensing represents a growing concern for governments, patients, taxpayers, and the pharmaceutical producers of innovative drugs.

A. Health Care as a Human Right and Government Health Care

A fundamental human right to health care, along with national mandates to provide comprehensive health coverage, continues to develop. The U.N. Universal Declaration of Human Rights asserted in 1948 that "[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and *medical care*."⁸⁰ The right to health care has been further elaborated in the International Covenant on Economic, Social and Cultural Rights,⁸¹ as well as the Convention on the Rights of the Child,⁸² the Convention on the Elimination of All Forms of Discrimination Against Women,⁸³ the International Convention on the Elimination of All Forms of Racial Discrimination,⁸⁴ and the Yogyakarta Principles.⁸⁵ In light of the

80. Universal Declaration of Human Rights art. 25.1, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III), at 76 (Dec. 10, 1948) (emphasis added).

81. International Covenant on Economic, Social and Cultural Rights art. 12, *opened for signature* Dec. 16, 1966, 993 U.N.T.S. 3 (recognizing "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and requiring parties to prevent, treat, and control epidemics and assure access to "medical service and medical attention in the event of sickness").

82. Convention on the Rights of the Child art. 24.1, *opened for signature* Nov. 20, 1989, 1577 U.N.T.S. 3 ("Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.").

83. Convention on the Elimination of All Forms of Discrimination Against Women art. 12.1, *opened for signature* Dec. 18, 1979, 1249 U.N.T.S. 13 ("States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning."). *Id.* art. 14.2(b) ("States Parties shall take all appropriate measures to eliminate discrimination against women in rural areas in order to ensure . . . access to adequate health care facilities, including information, counseling and services in family planning[.]").

84. International Convention on the Elimination of All Forms of Racial Discrimination art. 5(e)(iv), *opened for signature* Dec. 21, 1965, 660 U.N.T.S. 195 ("States Parties undertake to prohibit and to eliminate racial discrimination in all its forms and to guarantee the right of everyone . . . [t]he right to public health [and] medical care.").

85. YOGYAKARTA PRINCIPLES ON THE APPLICATION OF INTERNATIONAL HUMAN RIGHTS LAW IN RELATION TO SEXUAL ORIENTATION AND GENDER IDENTITY 22 (2007),

tension between IP rights and access to health care,⁸⁶ the U.N. High Commissioner of Human Rights recognized that “there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other.”⁸⁷

A specific human right to health care has also been widely accepted at the national level, with more than seventy states incorporating provisions guaranteeing a right to health care into their constitutions or statutes.⁸⁸ For example, Thailand’s constitution states:

A person shall enjoy an equal right to receive proper and standard public health service, and the indigent shall have the right to receive free medical treatment from public health centers of the State . . . A person shall have the right to receive proper prevention and eradication of harmful contagious diseases without charge in a timely manner.⁸⁹

South Africa similarly recognizes a right to health care in its constitution, charging the government to “take reasonable legislative and other measures . . . to achieve the progressive realisation of [the right to health care].”⁹⁰ Brazil constitutionally declares that “[h]ealth is a right of all and a duty of the State.”⁹¹ Canada takes a less-committal stance, pledging only to “facilitate reasonable access to health services without financial or other barriers.”⁹² Even the United States, long resistant to the idea of health care reform, is approaching the idea that everyone is entitled to at least a minimum level of health care.⁹³

http://www.yogyakartaprinciples.org/principles_en.pdf (Principle 17: “The Right to the Highest Attainable Standard of Health”).

86. See, for example, the discussion of compulsory licensing by South Africa and Thailand, *supra* Part I.

87. Sub-Commission on the Promotion and Protection of Human Rights Res. 2000/7, Intellectual Property Rights and Human Rights, 52d Sess., Aug. 17, 2000, U.N. Doc. E/CN.4/SUB.2/RES/2000/7 (Aug. 17, 2000).

88. Wesley A. Cann, Jr., *On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply Under a Theory of Progressive Global Constitutionalism*, 25 U. PA. J. INT’L ECON. L. 755, 846–47 (2004).

89. CONSTITUTION OF THE KINGDOM OF THAILAND, § 51 (2007).

90. S. AFR. CONST., ch. 2, § 27, 1996.

91. CONSTITUIÇÃO FEDERAL [C.F.][CONSTITUTION] art. 196 (Braz.).

92. Canada Health Act, R.S.C. 2009, c. C-6, § 3.

93. See Sheryl Gay Stolberg & Robert Pear, *Obama Signs Health Care Overhaul Bill, with a Flourish*, N.Y. TIMES, Mar. 23, 2010, <http://www.nytimes.com/2010/03/24/health/policy/24health.html>.

When health care is a government-run and government-funded enterprise,⁹⁴ compulsory licenses issued by the government for medicines appear to fall squarely within the meaning of public non-commercial use.⁹⁵ Government health care programs distribute drugs to their citizens, making the use public, while also providing those drugs free of charge or on a non-profit basis, making the use non-commercial.⁹⁶ With broad and poorly funded⁹⁷ governmental mandates to provide public health care spanning the globe, compulsory licensing poses a tempting option to increase drug availability while maintaining low costs.⁹⁸

B. The Pharmaceutical Development Outlook⁹⁹

Government health care programs, however, when combined with compulsory licensing and important pharmaceutical markets, represent a corresponding threat to the current R&D infrastructure of drug

94. See, e.g., Lei No. 8.080, de 19 de Setembro de 1990, DIÁRIO OFICIAL DA UNIÃO [D.O.U.] de 20.09.1990 (Braz.); Canada Health Act; National Health Policy, 1983, Ministry of Health & Family Welfare (India); National Health Security Act B.E. 2545 (2000) (Thai.).

95. TRIPS art. 31(b).

96. See, e.g., Gold & Lam, *supra* note 19, at 25; Ho, *supra* note 13, at 402–04.

97. For example, Thailand spent only 3.7% of its Gross Domestic Product (GDP), Brazil spent 8.4%, and Canada spent 10.1% of its GDP on health care in 2007, while the United States spent 15.7%. *Health Expenditure, Total (% of GDP)*, WORLD BANK, <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS> (last visited Nov. 13, 2010). Many also maintain that health care may be poorly funded as a result of opportunistic governmental budget decisions. See, e.g., Stephanie Skees, Note, *Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?*, 19 PACE INT'L L. REV. 233, 243–45 (2007); *Bangkok's Drug War Goes Global*, *supra* note 23; *Theft in Thailand*, *supra* note 1.

98. See Reichmann, *supra* note 21, at 252 (“[T]he goal behind [Thailand’s] recent barrage of compulsory licenses was to move the relevant pharmaceutical companies from a ‘low volume-high margin’ pricing strategy to a ‘high volume-low margin’ alternative approach.”); Nopporn Wong-Anna, *Thailand Stuns Drug Firms with Generic Licenses*, REUTERS (U.K. ed.), Jan. 25, 2007, available at <http://uk.reuters.com/article/idUKSP1356620070125> (quoting the Thai Health Minister saying “[w]e have to do this because we have so many patients to treat with so little budget. We can’t watch our people die”); see also *Brazil Reaches with Abbott Labs in AIDS Drug Dispute*, ASSOCIATED PRESS, Oct. 12, 2005, available at Lexis Nexis Academic (describing how Brazil avoided issuing a compulsory license: “The price we reached is what the national AIDS program could pay.”). Thailand and Brazil are relatively wealthy nations, which suggests that few countries do not have similar health care budget problems. See *Gross Domestic Product 2009*, WORLD BANK, available at <http://siteresources.worldbank.org/DATASTATISTICS/Resources/GDP.pdf> (ranking Brazil eighth and Thailand thirty-third among all nations).

99. This Note presupposes that a patent-driven private pharmaceutical industry is better and preferable to purely public-funded governmental pharmaceutical innovation programs. Even should this not be the case, however, the same international R&D free-riding concerns remain present in such governmental programs unless a global contribution mechanism ensures that each nation carries its own burden in funding medical research. Such radical industry changes are beyond the scope of this Note, which attempts to address concerns regarding the current pharmaceutical R&D structure in the current international legal environment.

development, which is funded both by purchasers of pharmaceutical products and by taxpayers via public research entities. With only one of every 5,000–10,000 tested compounds reaching the market and taking an average of 11.8 years to get there,¹⁰⁰ drug R&D investment requires a high risk premium.¹⁰¹ Although the exact amount is disputed, current estimates to develop an innovative, new molecular entity drug range from \$802–\$868 million,¹⁰² and costs continue to rise.¹⁰³ Pharmaceutical development is also far from a purely private enterprise, with the NIH annually spending over \$31 billion in taxpayer dollars in basic medical research, which supports downstream drug development by the pharmaceutical industry.¹⁰⁴

100. CONGRESSIONAL BUDGET OFFICE, PUB. NO. 2589, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 20 (2006). Regulatory approval has also become increasingly risky, with the average time from drug discovery to market entry gradually lengthening. *See id.* at 22–23.

101. The capital asset pricing model measures the risk premium for a particular investment by comparing the expected return on that investment to the expected overall market return. ROBERT S. PINDYCK & DANIEL L. RUBINFELD, MICROECONOMICS 564–68 (7th ed. 2009); *see also* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 153 (2003) (explaining that in viewing R&D as an investment project, an investor must “know both the amount of expenditures and the timing of these expenditures, since funds committed to R&D . . . have both a direct cost and an opportunity cost”). An informal survey of major pharmaceutical firms yielded nominal “hurdle rates” (minimum acceptable rates of return) of 13.5% to over 20%. *Id.* at 163 n.22.

102. *See* DiMasi, *supra* note 101, at 180. The \$802 million estimate reflects total expenses, including failed research, clinical and approval expenses, opportunity costs of capital, and tax adjustments. *Id.* at 158–80. A subsequent study discovered that cost varied greatly by drug type and producer, noting that the final overall estimate of \$868 million “suggests, if anything, that \$802 million is an underestimate.” Christopher P. Adams & Van V. Branter, *Estimating the Cost of New Drug Development: Is It Really \$802 Million?*, 25 HEALTH AFFAIRS 420, 427 (2006).

Public Citizen, a non-governmental organization founded by Ralph Nader, however, estimated new drug costs in 2001 at \$71 million (after adjustments for R&D tax deductions). PUBLIC CITIZEN, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY’S “SCARE CARD” 6 (2001). Public contributions to pharmaceutical R&D may also be understated “because they do not include indirect funds such as tax expenditures . . . and additional periods of marketing exclusivity.” Kevin Outterson, *Should Access to Medicines and TRIPS Flexibilities Be Limited to Specific Diseases?*, 34 AM. J.L. & MED. 279, 287 (2008). Furthermore, public entities like NIH often subsidize much of the research that goes into a pharmaceutical product. For example, NIH spent an estimated \$484 million for paclitaxel-related research, including the development of Taxol, which has generated over \$9 billion in sales for a private pharmaceutical company, which in turn has paid back only a 0.5% royalty (\$35 million) to the NIH. U.S. GEN. ACCOUNTING OFFICE, GAO-03-829, TECHNOLOGY TRANSFER: NIH-PRIVATE SECTOR PARTNERSHIP IN THE DEVELOPMENT OF TAXOL 13–15 (2003) [hereinafter TAXOL REPORT].

103. CONGRESSIONAL BUDGET OFFICE, *supra* note 100, at 35–37 (tracking R&D expenditures by year against the number of new molecular entity drugs approved); *see also* DiMasi, *supra* note 101, at 154 (tracking pharmaceutical R&D expenditures).

104. *NIH Budget*, NAT’L INSTS. OF HEALTH, <http://www.nih.gov/about/budget.htm> (last visited Nov. 13, 2010). “Although only some of that spending was explicitly related to pharmaceuticals, much of it was for the basic research on disease mechanisms that underlies the

R&D therefore usually targets drugs that have an expected return high enough to generate substantial profit and fund subsequent R&D.¹⁰⁵ Because R&D investment decisions are guided by the expected economic return for a particular line of research, palatability of risk is proportional to the magnitude of the expected returns.¹⁰⁶ Assuming that research into risky, unexplored areas of health is desirable, low expected returns, whether due to a small market for a particular drug or weakened patent exclusivity rights as a result of compulsory licensing, may chill such R&D.

After a pharmaceutical drug runs the gamut of patenting, clinical trials, and regulatory approval procedures, the patent specification and a wealth of safety and efficacy data are available to the public, resulting in serious appropriability concerns.¹⁰⁷ In the absence of strong patent protection and regulatory data exclusivity, generic producers are able to rapidly reverse-engineer drugs, obtain regulatory approval by relying on

search for new drugs." CONGRESSIONAL BUDGET OFFICE, *supra* note 100, at 27. Not all developed countries contribute equal public funding to support pharmaceutical R&D, however. While the NIH spends over \$31 billion annually, its counterparts in Europe collectively spend only \$3–4 billion. Glen Whitman & Raymond Raad, Cato Inst., *Bending the Productivity Curve: Why America Leads the World in Medical Innovation*, POL'Y ANALYSIS, Nov. 18, 2009, at 5. Thus, U.S. taxpayers bear a disproportionately heavy burden in developing new pharmaceutical drugs. Some distributional concerns of compulsory licensing are explored further with regards to patient-shouldered and taxpayer-shouldered R&D burdens in Part II(C), *infra*.

105. See DRAHOS WITH BRAITHWAITE, *supra* note 7, at 167 ("Patent-based R&D is not responsive to demand, but to ability to pay," resulting in drugs for "mental illness, hypertension and erectile dysfunction, [but not for] tropical diseases"); DiMasi, *supra* note 101, at 163–64 (finding that nominal cost of capital estimates hover around fifteen percent); *see also* Sykes, *supra* note 36, at 62 ("A policy that requires the developers of [essential] drugs to sacrifice their intellectual property rents in the name of a "national emergency" or some similar moniker will simply discourage research in the areas where it has the most potential to yield high returns.").

Public R&D funding, with its limited ability to generate a return on investment, does not necessarily follow the same investment strategy. *See, e.g.*, TAXOL REPORT, *supra* note 102, at 13–15. Public R&D, however, is most often targeted at basic research, which private pharmaceutical companies build upon to bring commercial pharmaceutical products to market. *See, e.g.*, CONGRESSIONAL BUDGET OFFICE, *supra* note 100, at 27 (explaining that the government "focus[es] on basic research, while the drug industry concentrates on applied research and development"). The drugs that ultimately make it to consumers, therefore, generally reflect this market reality.

106. Whitman & Raad, *supra* note 104, at 8 ("Other things being equal, individuals and firms will tend to invest more in medical innovation when (a) they expect a larger return; (b) the returns will last for a longer period of time; and (c) the returns arrive sooner rather than later."); CONGRESSIONAL BUDGET OFFICE, *supra* note 100, at 44–45 ("Economists broadly agree that a reduction in profits would cause private-sector investment in drug R&D to grow more slowly or to decline."). *But see* Lazzarini, *supra* note 25, at 110–12 (noting that pharmaceutical companies both distribute more profits and spend more on marketing and administration than they devote to R&D of new drugs).

107. See CARLOS MARÍA CORREA, SOUTH CENTRE, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT 6–7 (2002).

the patent holder's safety and efficacy data, and sell the generic version on a competitive market against the innovative firm that incurred the stratospheric R&D and original regulatory approval costs.¹⁰⁸ Without such protection, the innovative pharmaceutical developer could expect little return on investment, and private R&D would dissipate.

Indeed, pharmaceutical appropriability in India resulted in a modified Indian pharmaceutical market devoid of R&D. In the Indian Patents Act of 1970, India abolished pharmaceutical compound patentability in favor of short seven-year pharmaceutical production-process patents, creating incentives to devise increasingly efficient production processes while permitting any manufacturer to produce the pharmaceutical compound itself.¹⁰⁹ Drug firms flooded the market as the number of licensed manufacturers grew from 2,237 enterprises in 1969–70 to an estimated 16,000 by 1992–93, illustrating that barriers to entry into the pharmaceutical market were not onerous.¹¹⁰ Profitability predictably plunged over that period, reducing R&D expenditures from 15.5% of sales prior to the 1970 Patents Act to a mere 1.4% in 1992–93 because of comparative declines in expected returns on R&D investment due to the absence of exclusivity for drug compounds.¹¹¹ 1.4% does not fund much R&D: India has become the world's leading generic pharmaceutical producer, but contributes little to the development of new pharmaceutical medicines.¹¹²

The most powerful developing countries followed India in prohibiting patent protection for pharmaceuticals. Between 1971 and 1996, Brazil prohibited patents for both pharmaceutical products and processes.¹¹³ Mexico and Argentina had similarly lowered pharmaceutical

108. See *id.*

109. DEERE, *supra* note 1, at 40; see also Carsten Fink, *Patent Protection, Transnational Corporations, and Market Structure: A Simulation Study of the Indian Pharmaceutical Industry*, in *INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH* 227, 229 (Carsten Fink & Keith E. Maskus eds. 2005).

110. Fink, *supra* note 109, at 229.

111. See *id.* at 231. By comparison, the American innovative pharmaceutical industry spends approximately 15.6% of sales on R&D. Danzon & Towse, *supra* note 25, at 184.

112. See Fink, *supra* note 109, at 221; *India's World Class Drug Manufacturers*, GLOBAL PHARMACY CAN., <http://www.globalpharmacycanada.com/India-Pharmaceutical-Industry-Information/indias-world-class-drug-manufacturers> (last visited Nov. 13, 2010) (describing its Indian drug sources and noting that "India is the single largest producer of generic medicine in the world"); Tremblay, *supra* note 12, at 11 (noting that Doctors Without Borders "obtains 80% of its AIDS medications from India"); see also THAI WHITE PAPER, *supra* note 2, at 8 (stating that Ranbaxy, an Indian generics manufacturer, was able to fill Thailand's order for 66,000 bottles of Efavirenz within a month).

113. CÍCERO GONTIJO, *CHANGING THE PATENT SYSTEM FROM THE PARIS CONVENTION TO THE TRIPS AGREEMENT: THE POSITION OF BRAZIL* 16 (Andrea Carina Ceschi trans., Heinrich Boll Found., Global Issue Paper No. 26, 2005).

patent protection prior to TRIPS.¹¹⁴ As a result, today only a handful of developed countries have a sufficiently sophisticated pharmaceutical industry and research base to conduct complex R&D.¹¹⁵

Compulsory licensing, if widely used as an escape-hatch from patent protection, presents a potential threat to continued research by relegating innovative producers to a level playing field with generic producers.¹¹⁶ Once a compulsory license is granted, licensees simply have to send a royalty check to the patent holder.¹¹⁷ These royalty payments are uniformly puny. For example, Indonesia offered a mere 0.5% royalty on the generic sale price for its HIV/AIDS compulsory licenses,¹¹⁸ Zambia offered 2.5%,¹¹⁹ and Mozambique offered 2%.¹²⁰ Meanwhile, Thailand has offered 0.5% to 2.0%.¹²¹

The pharmaceutical market has already encountered the likely bleak effects of widespread compulsory licensing and its low royalty rates. The post-1970 Indian pharmaceutical industry demonstrated that extremely low margins do not incentivize R&D.¹²² In a similar vein, the Egyptian pharmaceutical industry is currently discovering that its cost-plus price-setting system, using the costs of ingredients as the benchmark, establishes a profit ceiling that acts as a *de facto* limit on R&D

114. DEERE, *supra* note 1, at 39.

115. *Implications of the Doha Declaration*, *supra* note 36, at 19–20, 52 (listing Belgium, France, Germany, Italy, Japan, the Netherlands, Sweden, Switzerland, the United Kingdom, and the United States as countries with "sophisticated pharmaceutical industry and research base[s]"); KEITH E. MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY* 52 (2002) ("At the top [of the global pharmaceutical industry] lie a relatively small number of large multinational enterprises, headquartered in the United States, Switzerland, Germany, the United Kingdom, and Japan, that undertake virtually all the basic pharmaceutical research done by private entities.").

116. *E.g.*, compare Fink, *supra* note 109, at 231 (noting that profitability declined in India, after the Patents Act of 1970, from 15.5% of revenue in 1969–70 to 1% in 1991–92, matching R&D expenditures), with Danzon & Towse, *supra* note 25, at 184 (noting that the U.S. innovative pharmaceutical industry spends approximately 15.6% of sales on R&D).

117. DRAHOS WITH BRAITHWAITE, *supra* note 7, at 149 (quoting a representative for the semiconductor industry, which faced similar compulsory licensing issues during the Uruguay Round negotiations).

118. Keputusan Presiden Republik Indonesia Tentang Pelaksanaan Paten Oleh Pemerintah Terhadap Obat-Obat Anti Retroviral [Decree of the President Republic of Indonesia Regarding Patent Exploitation of Anti Retroviral Drugs by the Government], Presidential Decree No. 83, Oct. 5, 2004.

119. MINISTRY OF COMMERCE, TRADE AND INDUSTRY, COMPULSORY LICENSE NO. CL 01/2004, 2004, MCTI/104/1/1c (Zam.).

120. MINISTÉRIO DA INDÚSTRIA E COMÉRCIO [MINISTRY OF INDUSTRY AND COMMERCE], LICENÇA COMPULSIVA [Compulsory License] No. 01/MIC/04, 2004, REF&/GDNAI/DNI/MIC/04 (Mozam.).

121. THAI WHITE PAPER, *supra* note 2, at 11.

122. *See, e.g.*, Fink, *supra* note 109, at 229–31.

expenditures.¹²³ Limiting economic returns on pharmaceutical R&D through abusive compulsory licensing, especially if in one or more of the few countries with innovative pharmaceutical industries,¹²⁴ therefore poses a threat to continued R&D into unexplored areas of medicine.

*C. The Fading Wisdom of Relying on the Developed World
for Funding Pharmaceutical Research and Development*

Supporters of broad compulsory licensing are often quick to illustrate that the pharmaceutical industry makes the vast majority of its profits in developed countries,¹²⁵ while developing countries have historically taken a somewhat unproblematic free ride by producing generic versions in the absence of pharmaceutical patent protection.¹²⁶ Indeed, developing countries represent less than ten percent of sales for the world's top pharmaceutical companies.¹²⁷ Yet although widespread compulsory licensing in developing countries appears to represent a minor dent in R&D revenues, the market status quo is rapidly changing. Developing countries continue to grow rapidly as pharmaceutical markets, and are expected to account for forty-eight percent of market growth by 2013.¹²⁸

Developed countries, however, continue to fund almost all pharmaceutical R&D,¹²⁹ with the United States in particular subsidizing health care innovation for the rest of the world.¹³⁰ The United States accounts

123. Sahar Aziz, Note, *Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer, and Foreign Direct Investment Policy: A Case Study of Egypt's Pharmaceutical Industry*, 10 ILSA J. INT'L & COMP. L. 1 (2004).

124. See *Implications of the Doha Declaration*, *supra* note 36, at 19–20, 52; LISA SACHS, HUMAN RIGHTS CHALLENGES FACING ABBOTT LABORATORIES: RISKS AND RECOMMENDATIONS, INTERFAITH CENTER ON CORPORATE RESPONSIBILITY REPORT 2 (2007) (noting, while addressing human rights shortcomings in the pharmaceutical industry, that North America, Europe, and Japan accounted for eighty-seven percent of global pharmaceutical sales in 2005).

125. See, e.g., Sykes, *supra* note 36, at 61 (citing FREDERIC M. SCHERER, *INDUSTRY STRUCTURE, STRATEGY AND PUBLIC POLICY* 362–66 (1996)).

126. See, e.g., DEERE, *supra* note 1, at 37–40; Lazzarini, *supra* note 25, at 108; Reichmann, *supra* note 21, at 247–48.

127. DAVID CAMPBELL & MANDY CHUI, *IMS HEALTH, PHARMERGING SHAKE-UP: NEW IMPERATIVES IN A REDEFINED WORLD* 7 (2010) (noting that the world's top fifteen pharmaceutical firms derived just 9.4% of sales from developing countries, which included China, Brazil, India, Russia, and less-developed countries); SACHS, *supra* note 124, at 2 (“In 2005, North America, Europe and Japan accounted for 87% of global pharmaceutical sales.”).

128. CAMPBELL & CHUI, *supra* note 127, at 5 (also noting that seventeen emerging markets, “[s]uperpowered by China, shored by Brazil, Russia and India, and spurred by the impetus of the new . . . fast followers,” accounted for thirty-seven percent of market growth in 2009); Press Release, IMS Health, *IMS Forecasts Global Pharmaceutical Market Growth of 5–8% Annually Through 2014; Maintains Expectations of 4–6% Growth in 2010* (Apr. 20, 2010) [hereinafter *IMS Forecasts*] (confirming that the aggregate pharmaceutical market growth in developing countries through 2014 will be roughly equal to the aggregate growth in developed countries).

129. See, e.g., SACHS, *supra* note 124, at 2.

130. Whitman & Raad, *supra* note 104, at 8–9; see, e.g., Thomas Bodenheimer, *High and Rising Health Care Costs. Part 2: Technologic Innovation*, 142 ANNALS INTERNAL MED.

for a disproportionately large share of pharmaceutical sales worldwide, currently hovering around thirty-five to forty percent, and also contributes over \$31 billion in public R&D funding through the NIH.¹³¹ By comparison, most developed nations, including Canada and the European nations, employ governmental universal health care programs that stringently regulate costs and contribute far less in public R&D funding.¹³² Canada and the United Kingdom, for example, have successfully constrained health care costs through the use of global budgets,¹³³ which set health care expenditures in advance and are particularly cost-effective in single payer systems, where the government has "strong bargaining power vis-à-vis providers."¹³⁴ In contrast, the United States government pays only forty-six percent of all U.S. health care costs through single-payer programs like Medicaid and Medicare¹³⁵ and does not employ a global budget,¹³⁶ while overall health care costs continue to rise.¹³⁷

932, 932 (2005) [hereinafter Bodenheimer, *Part 2*] ("Because the spread of new technologies is relatively unrestrained in the United States, many of these technologies are used to a greater extent than in other nations, and the United States thereby incurs higher health care costs."); Jack A. Ginsburg et al., *Amer. Coll. of Physicians, Achieving a High-Performance Health Care System with Universal Access: What the United States Can Learn from Other Countries*, 148 *ANNALS INTERNAL MED.* 55 (2008); Kenneth Rogoff, *A Prescription for Marxism*, 146 *FOREIGN POL'Y* 74, 75 (2005).

131. See Whitman & Raad, *supra* note 104, at 5, 7 (noting that the United States has developed a greater number of pharmaceutical products than the European Union and vastly outspent the European Union on pharmaceutical products in terms of purchases and public R&D support, even though the European Union has an approximate population of 499 million while the United States has an approximate population of 307 million); IMS Forecasts, *supra* note 128 (noting that the global pharmaceutical market grew to \$837 billion in 2009, with the U.S. market growing to \$300 billion in 2009 and expected to grow to \$360–390 billion by 2014); *Total Unaudited and Audited Global Pharmaceutical Market By Region*, IMS HEALTH (Mar. 2009), http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/Global_Pharm_Market_by_Region.pdf (reporting that of the \$773.1 billion global pharmaceutical market in 2008, North America accounted for \$311.8 billion, while Europe accounted for \$247.5 billion).

132. See, e.g., Bodenheimer, *Part 2*, *supra* note 130, at 935; Whitman & Raad, *supra* note 104, at 5 (noting that the European Union annually spends only \$3–4 billion in total on public R&D).

133. Bodenheimer, *Part 2*, *supra* note 130, at 935.

134. *Id.*; Whitman & Raad, *supra* note 104, at 8.

135. Ginsburg et al., *supra* note 130, at 57; David Carey et al., *Health Care Reform in the United States* ¶ 11 (Org. for Econ. Co-operation & Dev., Econ. Dept. Working Paper No. 665, 2009).

136. Attempts to constrain public health care expenditures paid by governmental programs have largely failed. For example, "[f]or physician services, the effect of price reductions are partially offset by increases in the quantity of services provided. For every 1% reduction in Medicare physician fees, the volume of physician services increases by 0.56%." Thomas Bodenheimer, *High and Rising Health Care Costs. Part 3: The Role of Health Care Providers*, 142 *ANNALS INTERNAL MED.* 996, 997 (2005) [hereinafter Bodenheimer, *Part 3*].

137. See Thomas Bodenheimer, *High and Rising Health Care Costs. Part 1: Seeking an Explanation*, 142 *ANNALS INTERNAL MED.* 847, 847 (2005) [hereinafter Bodenheimer, *Part 1*]; IMS Forecasts, *supra* note 128.

As a rare holdout from extensive health care regulation in the developed world, the relatively unrestrained health care market in the United States has permitted rapid implementation of new health care technology,¹³⁸ including pharmaceuticals, for which the United States pays higher prices because of the lack of a centrally-organized health care system.¹³⁹ Without price regulations for pharmaceutical drugs, the American pharmaceutical market grew from equal the size of the European market at the beginning of the 1990s to nearly double the size of the European market by the end of the decade, becoming the "dominant source of innovation and innovative drugs, with Europe lagging behind."¹⁴⁰ The relatively open U.S. market also appears to influence European pharmaceutical R&D, because European firms can count on higher U.S. prices and earlier assimilation of new technology into the U.S. market than in the tightly regulated European market.¹⁴¹ An Organisation for Economic Co-Operation and Development (OECD) report explained:

[P]rice indexes of drugs in 12 countries indicate that foreign prices are up to 20% lower than public prices in the United States . . . This pricing pattern probably reflects the price controls imposed in many countries, but not in the United States, where the authorities do not interfere in the determination of drug prices . . . It might also, however, reflect less price elastic demand in the United States and, therefore, price discrimination by monopolistic (owing to patent protection) drug manufacturers. *Either way, the relatively high prices paid for patented drugs in the United States strengthen incentives for the devel-*

138. Bodenheimer, *Part 2, supra* note 130, at 933 ("Physicians in the United States expand the number of patients deemed eligible for new procedures more rapidly than do physicians in other nations, in part because the fee-for-service payments made to physicians and hospitals that use new diagnostic and therapeutic procedures are relatively generous." (citation omitted)); see Carey et al., *supra* note 135, ¶ 13 ("[T]he availability and use of sophisticated medical techniques [in the United States] is significantly higher than in most countries, except Japan.").

139. Whitman & Raad, *supra* note 104, at 8.

140. See ALFONSO GAMBARDELLA ET AL., *GLOBAL COMPETITIVENESS IN PHARMACEUTICALS: A EUROPEAN PERSPECTIVE* 28–29 (2000).

141. See Whitman & Raad, *supra* note 104, at 3 ("[P]harmaceutical companies in other countries might invest in new drugs with the expectation of marketing them in the United States . . . In this regard, it may prove difficult to isolate the effects of any given country's policies on innovation."). Indeed, European pharmaceutical firms have remained strong actors in the pharmaceutical market, although the U.S. industry has surpassed the European industry over the past decade, both in respect to the quantity and quality (i.e., first-in-class innovative drugs) of pharmaceutical drugs. GAMBARDELLA ET AL., *supra* note 140, at 28–29; Whitman & Raad, *supra* note 104, at 7.

*opment of more effective drugs, which also benefit patients in other (notably OECD) countries.*¹⁴²

Recent political developments, however, threaten to undermine the current structure of the global pharmaceutical market. In part due to high and rising pharmaceutical prices,¹⁴³ the United States has passed recent health care legislation mandating that most Americans obtain medical coverage by 2014.¹⁴⁴ Although the new health care legislation fails to implement a single-payer system or establish a global budget for government-funded health care, the failure to better constrain health care spending has generated extensive criticism.¹⁴⁵ As the United States takes initial steps to curb health care expenditures approaching twenty percent of its Gross Domestic Product (GDP),¹⁴⁶ extensive compulsory licensing by developing nations may increasingly lead patients and taxpayers in the United States and other developed countries to question why they should foot the astronomical bill for pharmaceutical development.¹⁴⁷ Such concerns especially arise if developing countries continue to spend far less than the United States on health care on a percentage-of-GDP basis, despite being the fastest growing markets.¹⁴⁸

Should the United States eventually institute a single-payer system, or should rising health care costs precipitate a consolidation of payer

142. Carey et al., *supra* note 135, ¶ 14. Pharmaceutical drugs make up ten percent of U.S. health care expenditures. Ginsburg et al., *supra* note 130, at 57; *see also* Whitman & Raad, *supra* note 104, at 8 (noting that prices for prescription drugs are thirty-five to fifty-five percent cheaper in Europe than in the United States).

143. *See* DiMasi, *supra* note 101, at 153–54; Carey et al., *supra* note 135, ¶ 14; CONGRESSIONAL BUDGET OFFICE, *supra* note 100, at 35–37.

144. Robert Pear, *Changing Stance, Administration Now Defends Insurance Mandate as a Tax*, N.Y. TIMES, July 17, 2010, <http://www.nytimes.com/2010/07/18/health/policy/18health.html>.

145. *See, e.g.*, Steve Holland, *Obama: Healthcare Will Need Adjustments To Cut Costs*, REUTERS, Mar. 29, 2010, available at <http://www.reuters.com/article/idUSTRE62N61Y20100329>; Megan McCardle, *The Health Care Reform Already Costs More Than We Thought It Would*, ATLANTIC, May 14, 2010, <http://www.theatlantic.com/business/archive/2010/05/the-health-care-reform-already-costs-more-than-we-thought-it-would/56752/> (noting that the Congressional Budget Office estimated that the health care reform will cost \$115 billion more over the next ten years than previously thought). For a discussion on U.S. health care budget concerns, *see* Ginsburg et al., *supra* note 130, at 62–73 (detailing the glaring shortcomings in U.S. health care despite having the highest per capita health care spending). *But see* Whitman & Raad, *supra* note 104, at 2 (noting that U.S. health care “performs poorly in comparison to Europe, Australia, and Japan,” but illustrating that comparative national health care studies fail to account for contributions to health care innovation, an area where the United States is the dominant actor).

146. Ginsburg et al., *supra* note 130, at 56.

147. *See, e.g.*, Ronald A. Cass, *Drug Patent Piracy*, WALL ST. J., May 7, 2007, available at <http://www.aegis.org/news/wsj/2007/WJ070503.html> (suggesting that after the Thai and Brazilian compulsory licenses, “no one wants to be stuck with the extra cost that Thailand or Brazil isn’t paying”).

148. *See supra* note 97.

bargaining power, the United States will encounter budgetary issues similar to those of Europe and developing countries, threatening potential promises to provide comprehensive health care. With rising costs and increased regulation, compulsory licensing *could* pose as attractive an option to increase access to unaffordable drugs in developed nations as it does for developing countries currently engaging in compulsory licensing, like Thailand.¹⁴⁹ Thus, the health care budget concerns in the developed world and the increasing importance of developing country pharmaceutical markets makes abuse of compulsory licensing a significant threat to continued drug development, while simultaneously posing an attractive option to fulfill universal health care promises within budget constraints.¹⁵⁰

III. THE TRIPS CONTEXT FOR PUBLIC NON-COMMERCIAL COMPULSORY LICENSING

Despite the developed world's deteriorating reliability as the exclusive source of pharmaceutical R&D and the emergence of the developing world as a powerful market, scholars have often interpreted Thailand's recent actions as per se valid exercises of compulsory licensing because they appear to comply with the public non-commercial use provision.¹⁵¹ Scholars generally agree that public non-commercial use encompasses government use,¹⁵² and one particular trend has interpreted public non-commercial use as a nearly limitless justification for compulsory licensing.¹⁵³ A faithful interpretation of TRIPS Article 31(b) within its context, however, demonstrates that TRIPS should survive this challenge to its

149. Indeed, the United States has already threatened to issue a compulsory license to lower the price of a pharmaceutical drug, Cipro, during the 2001 anthrax scare. Carroll & Winslow, *supra* note 56.

150. See Whitman & Raad, *supra* note 104, at 11 (noting that experiences with Medicare and price controls, let alone compulsory licensing, demonstrate "that expanding government's role as purchaser of health care services, either by expanding existing government programs or creating new programs, would tend to reduce innovation in health care delivery").

151. See, e.g., Abbott & Reichmann, *supra* note 25, at 956 ("[T]here is little doubt that Thailand would win a dispute settlement action based on the TRIPS-compliance of its government use licensing."); Reichmann, *supra* note 21, at 256 ("[T]he Thai approach was a perfectly 'legitimate' exercise of the State's powers under the TRIPS Agreement, with a possible caveat for the low royalty paid."); Ho, *supra* note 13, at 441-42 (taking the lesser stance that Thailand's compulsory licenses were "not [yet] a situation where Thailand clearly violated TRIPS").

152. See, e.g., BLAKENEY, *supra* note 21, at 91; CORREA, *supra* note 21, at 316; Gold & Lam, *supra* note 19, at 25; Ho, *supra* note 13, at 402-04, 431-32; Marc, *supra* note 21, at 116; Reichmann, *supra* note 21, at 256.

153. See, e.g., CIPIH REPORT, *supra* note 22, at 35-36; Gold & Lam, *supra* note 19, at 25-30; Ho, *supra* note 13, at 402-04; Love, *supra* note 22, at 74.

harmonizing legal structure, prescribing a reasonable middle ground between providing immediate access to drugs and maintaining patent rights. Such a timely clarification will hopefully reduce obstructionism that hinders legitimate compulsory licensing in developing nations and clarify the boundaries of international patent rights for pharmaceutical investors and producers.

*A. Changing Winds: The Likelihood of a WTO Panel
Decision on TRIPS Article 31*

Although no WTO lawsuits regarding compulsory licensing are currently pending, recent events suggest that a clarifying WTO panel decision is no longer a completely unrealistic probability. To date, a WTO panel has yet to interpret the compulsory licensing provisions under TRIPS Article 31 because countries are notoriously risk averse in WTO litigation, strongly preferring to bring only "slam dunk" cases before WTO panels.¹⁵⁴ This is particularly the situation at the intersection of intellectual property rights and health care, which exists in an emotionally charged, policy-fraught maelstrom.¹⁵⁵ For example, after the political embarrassment of challenging South Africa's compulsory licenses for HIV/AIDS drugs, the United States has been reluctant to haul a developing country employing compulsory licenses before a WTO panel and "give credence to the idea of the WTO interfering with poor countries' health policies."¹⁵⁶ However, developed countries' improved

154. See J.H. Reichman & David Lange, *Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives To Facilitate Worldwide Intellectual Property Transactions*, 9 DUKE J. COMP. & INT'L L. 11, 48 (1998); see also Judith H. Bello, *Some Practical Observations About WTO Settlement of Intellectual Property Disputes*, 37 VA. J. INT'L L. 357, 358-59 (1997) (noting that electing to establish a panel raises expectations, and that accountable government lawyers and officials are unlikely to engage in WTO litigation unless there is a high probability of success, from both "a personal as well as institutional level"). Indeed, developed nations have generally only litigated TRIPS provisions before WTO panels when the conduct was particularly egregious, constituting an obvious "slam dunk" violation. See, e.g., Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, ¶¶ 4.2, 7.36, WT/DS114/R (Mar. 17, 2000) [hereinafter *Canada-Patent Protection*] (finding Canada in violation of its TRIPS obligations for abrogating the exclusive patent rights to make and use the patented subject matter under a Canadian law permitting generic firms to produce and stockpile drugs prior to patent expiration in order to facilitate generic entry into the pharmaceutical market); Panel Report, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶¶ 7.6, 7.41-43, 7.63, WT/DS50/R (Sept. 5, 1997) (finding India in violation of TRIPS where India failed to establish a "mailbox" system under TRIPS Article 70.8 to receive pharmaceutical patent applications as a temporary measure prior to implementing pharmaceutical patentability during India's TRIPS transition phase).

155. See *supra* Part I.A-B (discussing compulsory licensing by South Africa and Thailand).

156. *US, Brazil End WTO Case on Patents, Split on Bilateral Process*, 19 INSIDE U.S. TRADE, June 29, 2001, at 1-2. The United States took a long hiatus from TRIPS litigation against developing countries after the controversy surrounding South Africa, withdrawing

respect for the public health concerns of developing countries and increasing risk-tolerance in WTO litigation suggest that a WTO panel decision clarifying permissible compulsory licensing practices is more likely than ever before.

In the decade since the South Africa controversy, U.S. trade policy has grown increasingly conciliatory with respect to TRIPS flexibilities. For example, the United States was the first nation to approve the TRIPS amendment to allow parallel importation for pharmaceutical products under compulsory licenses,¹⁵⁷ which appears to conflict with U.S. attempts to bilaterally strengthen IP protection through Free Trade Agreements (FTAs).¹⁵⁸ In every post-2005 FTA, however, the United States has, at a minimum, signed a side letter of understanding affirming that the FTA's IP obligations "do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency."¹⁵⁹ Four of the five most recent FTAs have eschewed a side letter in favor of an operational FTA provision providing an explicit affirmation of commitment to the Doha Declaration.¹⁶⁰ The United States appears to have very willingly agreed

from a potential panel decision in a lawsuit against Brazil in 2001, and abstaining from litigation until bringing a lawsuit against China in 2007. *See* DEERE, *supra* note 1, at 156–58.

157. *See Intellectual Property (TRIPS) and Public Health: Members Accepting Amendment of the TRIPS Agreement*, WTO, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited Nov. 13, 2010).

158. The United States' attempts to obtain "TRIPS-plus" IP protection (i.e., IP protection above and beyond that required by TRIPS) abroad have been highly criticized as coercive attempts to "achieve [bilaterally] what was not possible to negotiate successfully at the multilateral [TRIPS negotiations]." Pedro Roffe & Christoph Spennemann, *The Impact of FTAs on Public Health Policies and TRIPS Flexibilities*, 1 INT'L J. INTEL. PROP. MGMT. 75, 76–77, 79 (2006); *see also* Frederick Abbott, Keynote Address at the ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines, *The Cycle of Action and Reaction: Latest Developments and Trends in IP and Health 5–7* (Oct. 13, 2004), *available at* http://ictsd.org/downloads/2008/08/abbott_bellagio3rev1.pdf. The United States currently has Free Trade Agreements (FTAs) incorporating TRIPS-plus provisions with Australia, Bahrain, Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Jordan, Morocco, Nicaragua, Oman, Peru, and Singapore, and has TRIPS-plus FTAs with Colombia, Korea, and Panama, pending approval by Congress. *See* DEERE, *supra* note 1, at 220–24; *Free Trade Agreements*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, <http://www.ustr.gov/trade-agreements/free-trade-agreements> (last visited Nov. 13, 2010).

159. *See, e.g.*, United States-Bahrain Free Trade Agreements, U.S.-Bahrain, Side Letter on Public Health, Sept. 14, 2004, 44 I.L.M. 544 (2005), *available at* http://www.ustr.gov/sites/default/files/uploads/agreements/fta/bahrain/asset_upload_file447_6296.pdf (reflecting the language of the Doha Declaration).

160. *See* Free Trade Agreement between the United States and the Republic of Korea, U.S.-S. Kor., art. 18.11, June 30, 2007, *available at* http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file273_12717.pdf (pending Congressional approval); United States-Panama Trade Promotion Agreement, U.S.-Pan., art. 15.12, June 12,

to such provisions: Colombia, having publicly declared that a FTA with the United States was its top foreign policy priority,¹⁶¹ obtained not one, but *two* public health provisions within its FTA.¹⁶²

The United States has also awakened from its TRIPS dispute resolution slumber, bringing an uncharacteristically risky lawsuit against China in 2007.¹⁶³ It made sweeping facial challenges to China's thresholds for criminal penalties and customs measures for enforcing its IP obligations,¹⁶⁴ for which little evidence of non-compliance existed.¹⁶⁵ Because the United States was already pressuring China bilaterally on strengthening its IP enforcement measures,¹⁶⁶ some wondered why the United States risked bringing the first-ever WTO lawsuit regarding IP enforcement measures, in which it appeared likely that China's measures were

2007, available at http://www.ustr.gov/sites/default/files/uploads/agreements/fta/panama/asset_upload_file131_10350.pdf (pending Congressional approval); United States-Colombia Trade Promotion Agreement, U.S.-Colom., art. 16.13, Nov. 22, 2006 [hereinafter Colombia FTA], available at http://www.ustr.gov/webfm_send/1336 (pending Congressional approval); United States-Peru Trade Promotion Agreement, U.S.-Peru, arts. 16.10(2)(e), 16.13, Apr. 12, 2006, available at http://www.ustr.gov/webfm_send/1031.

161. DEERE, *supra* note 1, at 172.

162. The Colombia FTA has a general provision recognizing the Doha Declaration and the availability of measures to protect public health, much like the Peru, Panama, and Korea FTAs. The second provision is within the data exclusivity provision, apparently to address concerns that TRIPS-plus periods of data exclusivity may pose an obstacle for compulsory licensing. Columbia FTA, *supra* note 160, arts. 16.10(2)(e), 16.13; Roffe & Spenneman, *supra* note 158, at 85 (suggesting that data exclusivity provisions "[have] been interpreted as possibly precluding governments' possibilities to use compulsory licensing"); Carsten Fink, *Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements*, TRADE NOTE (World Bank), Feb. 7, 2005, at 2 (also suggesting that data exclusivity may pose an "obstacle for governments to effectively use compulsory licensing").

163. See Request for Consultations by the United States, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/1 (Apr. 16, 2007). China is in a relatively nascent stage of WTO membership. See *China-Member Information*, WTO, http://www.wto.org/english/thewto_e/countries_e/china_e.htm (last visited Nov. 13, 2010) (noting that China has been a WTO Member since Dec. 11, 2001).

164. Panel Decision, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, ¶ 2.2, WT/DS362/R (Jan. 26, 2009) [hereinafter *China Panel Report*].

165. The United States facially challenged China's provisions detailing customs and criminal measures "as such," rather than challenge specific Chinese IP practices, *id.* ¶¶ 7.212, 7.416, for which evidence appears to have been scarce. See, e.g., *id.* ¶¶ 7.616–17 (noting that the United States submitted a U.S. newspaper article, a statistic from a management consultant report, and a *Time* magazine article to support its assertion that China's criminal thresholds are inconsistent with TRIPS Article 61. The Panel found that "even if these sources were suitable for the purpose of demonstration of contested facts in this proceeding, the information that was provided was too little and too random").

166. China has resided on the Priority Watch List since 2005. 2010 USTR SPECIAL 301 REP. 3; 2009 USTR SPECIAL 301 REP. 5; 2008 USTR SPECIAL 301 REP. 19; 2007 USTR SPECIAL 301 REP. 18; 2006 USTR SPECIAL 301 REP. 16; 2005 USTR SPECIAL 301 REP. 15.

compliant with minimum TRIPS standards.¹⁶⁷ Indeed, the WTO Panel adhered closely to the text of the relevant TRIPS provisions, finding that the United States failed to establish that China's criminal thresholds were inconsistent with TRIPS obligations, and that China's customs measures were also mostly compliant.¹⁶⁸

Thus, the United States appears willing to engage the WTO dispute resolution system to clarify TRIPS obligations despite the risk of an unfavorable ruling, while its FTAs demonstrate a heightened respect for TRIPS flexibilities.¹⁶⁹ As such, a lawsuit regarding compulsory licensing may appear to be a legitimate attempt to clarify permissible compulsory licensing practices under TRIPS, and not so much an inhumane attack on a developing nation's health policies. Although compulsory licensing activity has chilled since the Thai compulsory licenses in 2008, behind-the-scenes activity reveals that compulsory licensing is still at the forefront of public health action.¹⁷⁰ With Thailand maintaining a wish list of drugs for which to issue compulsory licenses¹⁷¹ and Ecuador mobilizing

167. See, e.g., Konstantina K. Athanasakou, Note, *China IPR Enforcement: Hard as Steel or Soft as Tofu? Bringing the Question to the WTO under TRIPS*, 39 GEO. J. INT'L L. 217, 225 (2007).

168. The Panel found that except for the hypothetical possibility that China's customs measures permit the release of seized goods back into "the channels of commerce" after a simple removal of an infringing trademark, China's customs measures were not inconsistent with TRIPS obligations under Article 59. *China Panel Report*, *supra* note 164, ¶ 7.395. The Chinese custom measures permitted confiscated infringing goods to be (1) donated for "social public welfare undertakings," (2) assigned to the IP right-holder, (3) auctioned after "eradicating the infringing features," or (4) destroyed. *Id.* ¶ 7.193. Note that the United States prevailed on a third facial challenge to China's copyright law, which denied copyright protection to prohibited/censored works. The Panel unsurprisingly found that China's "entire ban on publication of a work" is not a form of effective copyright protection that complies with TRIPS obligation under Article 9.1. *Id.* ¶¶ 7.180–81.

169. See Athanasakou, *supra* note 167, at 223–25 (citing USTR statements that the United States finds IP enforcement one of China's greatest shortcomings, and quoting E.U. representatives stating "[t]his is a case of great importance We will watch developments in these consultations with great interest' as the EU is China's largest trading partner").

170. Thailand continues to extend its existing compulsory licenses. See Editorial, *The Licensing of Key Drugs*, BANGKOK POST, June 16, 2010, <http://www.bangkokpost.com/opinion/opinion/38827/the-licensing-of-key-drugs>. Also, Ecuador is currently positioning itself to issue compulsory licenses. Decreto No. 118 [Decree No. 118], 23 de Octubre de 2009 (Ecuador) [hereinafter Ecuadorian Presidential Decree No. 118] (declaring that access to medicines is in the public interest, and that compulsory licenses may be granted for medicines necessary for treatment).

171. See THAI WHITE PAPER, *supra* note 2, at 2 (noting that Thai citizens are entitled to full access to 900 drugs, many patented, on the government's essential drugs list); Cohen, *supra* note 1 (quoting one economist as saying "[t]here's a big push in Thailand to [issue compulsory license] for everything"); Zamiska, *supra* note 2 (noting that "there are more products for which the government may allow [compulsory licenses]," including other cardiovascular and cancer drugs). Thailand continues to extend its compulsory licenses, *The Licensing of Key Drugs*, *supra* note 170, and is presently hoping for a WTO solution regarding compulsory licensing and low-cost generic drugs, suggesting that Thailand is far from dor-

to issue compulsory licenses of its own,¹⁷² a willing complainant and willing provokers appear to exist, making an analysis of public non-commercial use under TRIPS Article 31 a timely endeavor.

B. *The Standard for Interpreting TRIPS*

When a TRIPS dispute precipitates a WTO lawsuit, the Dispute Settlement Understanding (DSU) applies.¹⁷³ Under the DSU, WTO dispute resolution panels must interpret TRIPS provisions according to the "customary rules of interpretation of public international law," in order to provide "security and predictability to the multilateral trading system."¹⁷⁴

These customary rules are set forth in the Vienna Convention on the Law of Treaties (VCLT),¹⁷⁵ which eschews policy arguments in favor of adhering to the text representing the outcome of treaty negotiations.¹⁷⁶ First, under VCLT Article 31, "[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."¹⁷⁷ Thus, interpretation under the Vienna Convention is both textual and purposive, with the relevant context for interpretation including the preamble and any subsequent agreements.¹⁷⁸ However, when interpretation

mant in the area of compulsory licensing. Ying Huang, *Thailand Could Seek WTO Solution on Compulsory Licensing, Generic Drugs*, PHARMASIA NEWS, Mar. 29, 2010, http://www.tginfo.com/Publications/pdf/APR2010_TH_WTO_solution.pdf.

172. Ecuadorian Presidential Decree No. 118, *supra* note 170.

173. TRIPS art. 64.1.

174. Understanding on Rules and Procedures Governing the Settlement of Disputes art. 3.2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401.

175. Vienna Convention on the Law of Treaties art. 31, May 23, 1969, 1155 U.N.T.S. 331 [hereinafter VCLT]. WTO panels and the Appellate Body recognize that "[t]he general rule of interpretation, expressed in Article 31 of the Vienna Convention, and the rules on supplementary means of interpretation in Article 32 of the Vienna Convention, have attained the status of rules of customary or general international law." *China Panel Report*, *supra* note 164, ¶ 7.500. Membership in the Vienna Convention is not universal: the United States is not a signatory of the VCLT, although it considers much of the VCLT to "constitute customary international law on the law of treaties." *Vienna Convention on the Law of Treaties*, U.S. DEPT. OF STATE, <http://www.state.gov/s/l/treaty/faqs/70139.htm> (last visited Nov. 13, 2010).

176. See VCLT, *supra* note 175, art. 31; Ho, *supra* note 13, at 387; see also Bello, *supra* note 154, at 365 ("[I]t is the outcome of the [Uruguay Round] negotiations that must control the deliberations of any dispute settlement panel. . . . There is no constructive role for judicial activism in the WTO dispute settlement system."). This conservatism plays out both ways in practice, however, because panels appear reluctant to find TRIPS violations without an explicit textual reason. See, e.g., *infra* text accompanying note 220.

177. VCLT, *supra* note 175, art. 31.1; see also *Canada-Patent Protection*, *supra* note 154, ¶ 7.12. The Doha Declaration mirrors the language of the VCLT: "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles." Doha Declaration, *supra* note 8, ¶ 5(a).

178. VCLT, *supra* note 175, arts. 31.2, 31.3.

under VCLT Article 31 “leaves the meaning ambiguous or obscure; or leads to a result which is manifestly absurd or unreasonable,” a panel may refer to the preparatory work of a treaty or the circumstances of its conclusion to either confirm an apparent VCLT Article 31 meaning or to substantively determine the meaning.¹⁷⁹

*C. Relevant Context Under the Vienna Convention:
TRIPS Preamble, Objectives, & Principles*

An analysis of the relevant context under the VCLT must recognize that TRIPS is first and foremost a treaty element of the World Trade Organization, as the preamble explains:

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade. . . .¹⁸⁰

By aiming to reduce distortions and impediments to international trade, the overarching purpose of TRIPS is to harmonize IP protection among WTO Members. Recognizing that IP concerns vary by stage of economic development, however,¹⁸¹ the preamble avoids a cookie-cutter approach to IP protection by addressing the “developmental and technological objectives” of IP protection and “the special needs of the least-developed country Members in respect of maximum flexibility in the

179. *Id.* art. 32.

180. TRIPS pmbl.

181. IP rights “tend to strengthen as economic development and incomes rise,” because “[a]s an economy’s technological sophistication increases, inventors and creators require stronger protection for their works; thus, demand for [IP rights] rises.” MASKUS, *supra* note 115, at 102. *Cf. id.* at 102–09 (further explaining, however, that mapping strength of IP rights against Gross National Product (GNP) results in a U-curve, illustrating that middle-income countries, such as Thailand, Brazil, and Mexico, have lower-than-expected IP protection). South Korea is an excellent example of how IP protection strengthens as an economy develops. *See* DRAHOS WITH BRAITHWAITE, *supra* note 7, at 102–04 (illustrating South Korea’s rapid evolution from being IP-protection-resistant to making an “[impressive] commitment to intellectual property,” in large part due to the rapid development of Korean technology- and patent-driven corporations like Samsung). *See generally* International Workshop on the Information Revolution and Economic and Social Exclusion in Developing Countries, Maastricht, Neth., Oct. 23–25, 1996, *Implications of Intellectual Property Rights for the Access to and Use of Information Technologies in Developing Countries*, at 29 (by Carlos M. Correa) [hereinafter *Implications of Intellectual Property Rights*] (“The semiconductor industry is highly concentrated. A few transnational corporations account for the overwhelming share of semiconductor production . . . Among developing countries, only South Korea has emerged as a world-class competitor.”).

domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base."¹⁸²

The "Objectives" articulated in Article 7 reinforce this notion of balance in TRIPS:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.¹⁸³

Thus, Article 7 provides an operational treaty provision establishing that IP protection is not a one-way street for protecting private patent rights, nor for free dissemination of patented technology to users.¹⁸⁴ Rather, the crucial balance to be achieved is defined as "mutual advantage."¹⁸⁵ Mutual advantage, however, requires defining the boundaries in which such advantage should occur. In the view that TRIPS "was an agreement [within the WTO] that was negotiated on the basis of *quid pro quos* among states," such that "[e]ach state gave something and got something," mutual advantage has already been assured.¹⁸⁶ Under that view, even if TRIPS generates no benefit for a developing country, the gains secured via increased market access by virtue of WTO membership makes mutual advantage a non-issue.¹⁸⁷ The TRIPS "Objectives" detail a subtler arrangement, however, by placing mutual advantage within the purview of "the protection and enforcement of intellectual property rights,"¹⁸⁸ requiring that TRIPS be internally mutually advantageous.¹⁸⁹ This comports with the balancing performed in the preamble.

182. TRIPS pmbl.

183. *Id.* art. 7.

184. See, e.g., INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 13 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 2d ed. 2008) [hereinafter CORREA & YUSUF] ("[These objectives] serve as a reminder that the TRIPS Agreement is not simply about the granting of rights to creators and innovators, but that such rights have to be balanced by measures conducive to social and economic welfare.").

185. TRIPS art. 7.

186. See Bruce A. Lehman, *Intellectual Property Rights as a Trade, Health and Economic Development Issue*, 17 ST. JOHN'S J. LEGAL COMMENT. 417, 417 (2003).

187. See *id.* at 419.

188. TRIPS art. 7.

189. See, e.g., CORREA & YUSUF, *supra* note 184, at 12–13 (noting that TRIPS Article 7 "embodies an international recognition of the primary public-policy objectives for which governments grant protection and enforcement to [intellectual property rights]" (emphasis added)).

The Article 8 “Principles” similarly emphasize a balance of rights and obligations, permitting the use of TRIPS flexibilities within certain constraints:

1. Members may, in formulating or amending their law and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.¹⁹⁰

Article 8.1 explicitly justifies a nation’s use of TRIPS flexibilities to protect public health, balanced by a condition of necessity.¹⁹¹ Just as Article 8.2 puts a responsibility on IP owners by suggesting that “[a]ppropriate measures . . . may be needed to prevent the abuse of intellectual property rights by right holders” with regard to public health situations or in sectors of vital importance, the necessity condition places a corresponding duty on a Member exercising TRIPS flexibilities to not unnecessarily undermine the harmonization of IP rights within the WTO system, as also reflected in the preamble and Article 7.¹⁹²

D. Article 31: Compulsory Licensing

Keeping in mind the contextual TRIPS objectives of facilitating trade through harmonizing IP protection and achieving mutual advantage for producers and users of innovative technology, Article 31 authorizes compulsory licensing as one of the flexibilities that may be appropriate

190. TRIPS art. 8.

191. See, e.g., NUNO PIRES DE CARVALHO, *THE TRIPS REGIME OF PATENT RIGHTS* ¶¶ 8.4–9 (2d ed. 2005) (arguing that “measures must be *necessary* to protect public health and nutrition,” and illustrating that necessity is especially important with regard to non-violation complaints); [7 WTO–TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS] MAX PLANCK COMMENTARIES ON WORLD TRADE LAW 197 (Peter-Tobias Stoll et al. eds., 2006) [hereinafter STOLL] (“[A] measure is necessary only if, among the effective measures, it is the one which restricts interstate trade the least.”); Gold & Lam, *supra* note 19, at 22–23.

192. TRIPS art. 8.1 (permitting Members to adopt measures necessary to protect public health “provided that such measures are consistent with the provisions of this Agreement”); see also CARVALHO, *supra* note 191, ¶ 31.2; STOLL, *supra* note 191, at 189, 197 (also noting the interconnected nature of TRIPS Articles 7 and 8).

under certain circumstances to achieve those goals.¹⁹³ Members have sovereign discretion to decide the most effective method of utilizing a compulsory license, either by permitting a government to use the patent subject matter itself or by issuing the license to an authorized third party, such as a generic pharmaceutical company.¹⁹⁴

Eleven of the twelve Article 31 provisions include important restrictions on compulsory licensing, but which are easily complied with and pose no substantial hurdle for a Member authorizing a compulsory license.¹⁹⁵ For example, non-exclusivity,¹⁹⁶ non-assignability,¹⁹⁷ and considering licenses on their "individual merits" prevent flagrant abuse of compulsory licensing,¹⁹⁸ while judicial review of compulsory license authorization provides a degree of due process to the patent holder.¹⁹⁹ Such provisions essentially amount to a box-checking exercise for a government desiring to avoid a WTO panel while improving access to pharmaceutical drugs. Rather, the provision providing the strictest restrictions on compulsory licensing is Article 31(b), which states:

[Compulsory licensing] may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a

193. Article 31 does not require that compulsory licensing be available; rather, it implicitly permits compulsory licensing by merely providing limits "[w]here the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder." TRIPS art. 31; Ho, *supra* note 13, at 395.

194. TRIPS art. 31 (permitting "use by the government or third parties authorized by the government"); CARVALHO, *supra* note 191, ¶ 31.2.

195. See, e.g., TRIPS art. 31(c) (requiring that "the scope and duration of such use shall be limited to the purpose for which it was authorized," which places some limits on compulsory licenses designed to confront a particular, discrete problem). For example, if a Member authorized a compulsory license for Ciproflaxin to combat bird flu, it arguably may not supply the drug under the same compulsory license to citizens suffering from swine flu. And if the bird flu problem is eradicated, the compulsory license presumably loses its effectiveness under Article 31(c). Neither of these Article 31(c) situations poses an onerous burden, however, since the Member could simply issue a second compulsory license to combat swine flu. Also, the drugs currently under compulsory licenses treat HIV/AIDS, heart disease, and cancer, none of which appear likely to be eradicated within the duration of those patents' drugs. See Ho, *supra* note 13, at 395–96 ("The bulk of Article 31 relates to procedural requirements . . . likely to be non-issues in most cases.").

196. TRIPS art. 31(d) (protecting a patent holder from being excluded from his own registered invention and allowing the patent holder to compete against the beneficiary of the compulsory license).

197. *Id.* art. 31(e) (preventing a compulsory license granted under the restrictive Article 31 conditions from entering the public marketplace, where it may be used for purposes beyond its original purpose).

198. *Id.* art. 31(a).

199. *Id.* arts. 31(g), 31(i), 31(j).

Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.²⁰⁰

Faithfully rephrasing Article 31(b) clarifies the three permissible situations for compulsory licensing: a Member may issue a compulsory license (1) when reasonable commercial negotiations have failed; (2) without prior negotiation when a national emergency or other circumstance of extreme urgency has arisen; or (3) without prior negotiation when the compulsory license is for "public non-commercial use."²⁰¹

First, failure to successfully negotiate with the patent holder on reasonable commercial terms may permit a Member to issue a compulsory license.²⁰² This flexibility furthers the TRIPS principles and objectives by allowing compulsory licensing when producers fail to live up to their end of the TRIPS bargain by refusing to license technology on commercially reasonable terms in circumstances when TRIPS flexibilities are justified.²⁰³

Read in isolation, Article 31 appears to make a compulsory license a default option when reasonable commercial negotiations fail. Such an interpretation, however, reads any patent right of exclusivity granted to the patent holder out of the TRIPS Agreement,²⁰⁴ because "[t]he essence of the patent right is to say 'no' to third parties."²⁰⁵ Remedying market failure cannot extend this far without reaching the "manifestly absurd or unreasonable"²⁰⁶ result of eviscerating the primary purpose of patents and depriving them of substantially all value. Article 8, for example, limits

200. *Id.* art. 31(b).

201. *Id.*; see also DEERE, *supra* note 1, at 82; Ho, *supra* note 13, at 400.

202. TRIPS art. 31(b).

203. See *id.* arts. 7–8; *supra* Part III(C). For similar reasons, compulsory licensing is also permissible to remedy commercial practices judicially or administratively determined to be anti-competitive. TRIPS art. 31(k); see also Taubman, *supra* note 25, at 931–32.

204. TRIPS art. 28.1(a) ("A patent shall confer on its owner the following exclusive rights: where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product.").

205. CARVALHO, *supra* note 191, ¶¶ 31.4, 31.8 (also stating that with regard to licensing intellectual property, "there is no sounder business practice than refusing to engage in commercial deals with competitors").

206. See VCLT, *supra* note 175, art. 32(b).

the use of TRIPS-consistent flexibilities to situations when they are *necessary* to protect public health or to promote public interest in a sector of vital importance.²⁰⁷ This does not require, however, that compulsory licensing occur only in "exceptional" circumstances.²⁰⁸ A WTO panel would likely give a Member considerable leeway in determining necessity.²⁰⁹

Also, a state may issue a compulsory license without prior negotiation with the patent holder during a national emergency or other circumstance of extreme urgency.²¹⁰ Within a public health context, Article 31(b) recognizes that complicated international negotiations between governments and the pharmaceutical industry will likely result in harmful delays and lost lives when medicines are urgently needed.²¹¹ Article 31(b) is primarily concerned with notice to the patent owner under these circumstances.²¹²

Article 31 does not invade Members' spheres of sovereignty by prescribing limits on situations that constitute emergencies or circumstances of extreme urgency. Neither does it establish necessary subject matter grounds for issuing compulsory licenses. Rather, it permits flexibility for circumstances unforeseen during the Uruguay Round negotiations: "Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency."²¹³ Thus, TRIPS

207. TRIPS art. 8.1; CARVALHO, *supra* note 191, ¶¶ 8.5–.7; STOLL, *supra* note 191, at 197.

208. *Contra* CARVALHO, *supra* note 191, ¶ 31.4 (maintaining that compulsory licensing is so exceptional as to be irrelevant in addressing public health issues); Cass, *supra* note 147 ("The WTO rules make clear that compulsory licensing is to be used only in exceptional circumstances.").

209. WTO panels appear reluctant to intrude on a Member's sovereignty without a clear violation of treaty obligations, suggesting that amorphous terms and vague obligations may work in the favor of an accused nation. *See, e.g., China Panel Report, supra* note 164, ¶¶ 7.395, 7.681 (upholding China's internal criminal thresholds and the majority of China's customs measures because the United States did not establish textual inconsistency with vague TRIPS obligations).

210. TRIPS art. 31(b).

211. *See* CARVALHO, *supra* note 191, ¶¶ 31.13–.14 ("[T]he obligation of previously seeking a voluntary license is excused when circumstances lead to the conclusion that spending time with undertaking such negotiations would necessarily impair the desired outcome of the compulsory license—in other words, that the patented product would not arrive in time to remedy the situation.").

212. TRIPS art. 31(b) (requiring that when no prior negotiations are needed, "the right holder shall, nevertheless, be notified as soon as reasonably practicable," and that "the right holder shall be informed promptly").

213. *See* Doha Declaration, *supra* note 8, ¶ 5(c) ("it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency"); *Implications of the Doha Declaration, supra* note 36, at 13, 15 ("[T]he TRIPS Agreement has left room for flexibility at the national level . . . Though Article 31 refers to some of the possible ground

creates a procedure designed to allow Members to react to exigent circumstances for any reason necessary to protect public health, letting the harmonization and mutual benefit goals delineate limits on compulsory licensing under such circumstances.²¹⁴

Compulsory licensing in national emergencies or other circumstances of extreme urgency carries few restrictions. This is not to say, however, that a Member may declare any situation a national emergency and issue compulsory licenses with impunity: the harmonization goals, the notions of mutual advantage for producers and users, and the TRIPS Article 8 necessity restriction all apply here. Finding support for expansive compulsory licensing practices within “national emergency or other circumstances of extreme urgency” appears difficult because doing so reads “national emergency” and “extreme urgency” out of this very restriction.²¹⁵

IV. COMPULSORY LICENSING FOR PUBLIC NON-COMMERCIAL USE

Because nations likely cannot plausibly invent a national emergency every time they desire to issue a compulsory license, the public non-commercial use restriction has acquired increasing importance. Indeed, scholars increasingly suggest that public non-commercial use could be a gateway for expansive use of compulsory licenses under normal circumstances.²¹⁶ One branch of this trend finds an expansive justification for compulsory licensing in the vagueness of the “public non-commercial”

(such as emergency and anti-competitive practices) for issuing compulsory licenses, it leaves Members full freedom to stipulate other grounds.”).

214. See TRIPS pmbl., arts. 7–8; CARVALHO, *supra* note 191, ¶¶ 8.5–8.7; STOLL, *supra* note 191, at 197.

215. TRIPS does not specify the magnitude an emergency must reach to attain “national” scale, but such a clarification is beyond the scope of this Note. Engaging in a similarly impossible interpretation, the Panel in *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights* labored for forty-five paragraphs to resolve a similar question of magnitude in determining the point at which infringement of IP rights under TRIPS art. 61 occurs “on a commercial scale.” *China Panel Report*, *supra* note 164, ¶¶ 7.532–.577. The Panel reached a not-so-conclusive interpretation that “counterfeiting or piracy ‘on a commercial scale’ refers to counterfeiting or piracy carried on at the magnitude or extent of typical or usual commercial activity with respect to a given product in a given market.” *Id.* ¶ 7.577. Thus, determining whether an event or series of events has created an “emergency,” and whether that emergency has reached a “national” level is likely to result in a similarly unsatisfactory answer. The *China* Panel found, probably with relief, that “the United States had [not established] a prima facie case with respect to impact on the commercial marketplace.” *Id.* ¶ 7.661.

216. See CIPIH REPORT, *supra* note 22, at 20; Gold & Lam, *supra* note 19, at 25–26, 30; Ho, *supra* note 13, at 402–04; Reichmann, *supra* note 21, at 256.

language itself.²¹⁷ Another view restricts public non-commercial use to "government use," but concludes that governmental use compulsory licensing for pharmaceuticals similarly enables expansive compulsory licensing practices.²¹⁸ Either interpretation entices the interpreter to find pharmaceutical compulsory licensing for government health care programs per se valid because it appears to comply with TRIPS Article 31.²¹⁹

A proper VCLT interpretation of "public non-commercial use" reveals that such expansive readings are misleading. A proper textual interpretation, however, is not necessarily harmful to developing-country or public-health interests. The *China* Panel, adhering closely to the TRIPS text and upholding the vast majority of the Chinese customs and criminal measures, illustrated that adherence provides predictability and that WTO panels are reluctant to invade Member sovereignty without strong textual reason.²²⁰ Accordingly, a WTO panel would likely grant considerable leeway to an accused nation in determining whether a public non-commercial complies with TRIPS obligations, including whether it is necessary to protect public health.

A. Defining Public Non-Commercial Use

Defining "public non-commercial use" is by far the most difficult interpretation exercise of TRIPS Article 31(b): it is facially vague, it has no standard meaning in patent law, and no WTO panel has attempted to define the term.²²¹ Reading "public non-commercial use" in isolation, the term appears open-ended. Improperly resorting to a dictionary, combining separate definitions of "public" and "commercial," and failing to proceed much further generates this result.²²² Using a dictionary in this manner, public non-commercial use appears to include any use that is not for business, or perhaps not for profit, which relates in some way to a nation's citizens.²²³

However, having established a careful balance of IP rights and obligations as a means of achieving mutual benefit,²²⁴ it is unfaithful to the text to construe the Article 31(b) permissible situations for compulsory licensing²²⁵ to read: (1) when reasonable commercial negotiations have

217. See, e.g., Gold & Lam, *supra* note 19, at 25–26, 30; Ho, *supra* note 13, at 402–04.

218. See, e.g., Reichmann, *supra* note 21, at 256.

219. See, e.g., Ho, *supra* note 13, at 402–04, 431–32; Reichmann, *supra* note 21, at 256.

220. *China Panel Report*, *supra* note 164, ¶ 8.1.

221. See Ho, *supra* note 13, at 402–03.

222. See Gold & Lam, *supra* note 19, at 25–30; Ho, *supra* note 13, at 402–04.

223. See Gold & Lam, *supra* note 19, at 25–26; Ho, *supra* note 13, at 403.

224. See TRIPS arts. 7–8; *supra* text accompanying notes 180–192.

225. Compulsory licensing is permitted, as clarified earlier, (1) if "the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms

failed; (2) without prior negotiation when a national emergency or other circumstance of extreme urgency has arisen; or (3) “for any use relating in some way to a nation’s citizens that is not for business or profit-related purposes.”²²⁶ This broad interpretation of public non-commercial use reads any true restriction out of Article 31(b), swallowing the “national emergency or other circumstances of extreme urgency” language, rendering it effectively superfluous, and frustrating the carefully constructed balance of mutual advantage.²²⁷ To avoid such manifestly absurd results, WTO judicial bodies may only conclusively rely on a dictionary when the ordinary meaning is readily apparent and uncontroversial.²²⁸ For example, the *China* Panel used the dictionary to define “commercial” and “scale” separately, but rather than merely combining those definitions, it analyzed the objectives, purpose, and negotiating history of TRIPS for forty-five paragraphs to reach an appropriate definition of “commercial scale.”²²⁹ Here, simply combining the separate dictionary definitions of “public” and “commercial” similarly fails to consider the phrase “public non-commercial use” within its proper context.²³⁰

A simple internal reference to the rest of TRIPS Article 31(b) clarifies. Through inclusion in a list of restrictions including “national emergency” and “other circumstances of extreme urgency,” “public non-commercial use” should be far more than an illusory restriction under the doctrine of *noscitur a sociis*.²³¹ Further, when describing the notifica-

[over] a reasonable period of time;” (2) under a national emergency or other circumstance of extreme urgency; or (3) for public non-commercial use. See *supra* text accompanying note 201.

226. See Gold & Lam, *supra* note 19, at 25, 29 (finding the plain meaning of “public non-commercial use” unambiguous after cobbling together separate definitions of “public” and “commercial,” obviating the need to resort to the negotiating history of the text). The authors reason that because “the term ‘public non-commercial use’ is not defined in TRIPS, Member States would normally be free to interpret this term as they wish, subject only to respecting the rights and obligations contained in the Agreement,” which they seem to find negligible. *Id.* at 26. Cynthia Ho takes the more reasonable stand of suggesting that “each nation may define the term, unless and until such definition is clarified in a WTO dispute settlement proceeding,” which is what this Note attempts to anticipate. See Ho, *supra* note 13, at 404.

227. See TRIPS pmb., arts. 7, 8.

228. See, e.g., *China Panel Report*, *supra* note 164, ¶¶ 7.533–.535. As the *China* Panel noted, “dictionaries are a useful starting point for the analysis of ordinary meaning of a treaty term, but they are not necessarily dispositive . . . [T]he ordinary meaning of a treaty term must be seen in the light of the intention of the parties as expressed in the words used by them against the light of the surrounding circumstances.” *Id.* ¶ 7.559 (internal quotation marks omitted).

229. *China Panel Report*, *supra* note 164, ¶¶ 7.533–.577.

230. See VCLT, *supra* note 175, arts. 31, 32.

231. BLACK’S LAW DICTIONARY 1087 (8th ed. 2004) (defining *noscitur a sociis* as a canon of construction suggesting that “the meaning of an unclear word or phrase should be determined by the words immediately surrounding it”—literally—“it is known by its associates”).

tion process, Article 31(b) states that "[i]n the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly."²³² Because Article 31(b) itself describes public non-commercial use as use by "the government or contractor," not merely suggesting government use as one possible type of public non-commercial use, the plain language of Article 31(b) establishes that public non-commercial use is best defined approximately as "use by the government" or "government use."²³³ Such a reading, aside from best comporting with the text itself, also creates a restriction more on par with national emergencies and other situations of extreme urgency.

Consulting the TRIPS preparatory materials also supports an interpretation closely limited to government use.²³⁴ Unfortunately, the Brussels Draft of TRIPS described "public non-commercial use" as "public non-commercial use."²³⁵ The later Draft of July 23, 1990, however, represented the U.S. negotiating position and advocated minimizing compulsory licensing, providing explicit grounds for compulsory licensing for "the possibility of exploitation of the patented invention by the government, or by third persons authorized by it," which suggests a governmental exploitation for a public non-commercial use compulsory license.²³⁶ This language appears in the first paragraph of TRIPS Article 31, which includes "use by the government or third parties authorized by the government."²³⁷ Yet within Article 31(b), "public non-commercial use" appears in one draft but not an earlier draft that strongly limited compulsory licensing, leaving the analysis incomplete.

232. TRIPS art. 31(b).

233. *Id.* (emphasis added); see also BLAKENEY, *supra* note 21, at 91–92.

234. See VCLT, *supra* note 175, ¶ 32. This is a standard interpretation move within the WTO dispute resolution process. See *China Panel Report*, *supra* note 164, ¶ 7.500 (noting that Articles 31 and 32 of the Vienna Convention "have attained the status of rules of customary or general international law"). The *China Panel* indeed resolved ambiguity in its decision "by reference to the records of the negotiation of the TRIPS Agreement." *Id.* ¶ 7.260 (referring in note 252 to Article 32 of the Vienna Convention).

235. GATT Trade Negotiations Committee, *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations: Revision (Brussels Draft)* art. 34(o), MTN.TNC/W/35/Rev.1 (Dec. 3, 1990), reprinted in GERVAIS, *supra* note 26, at 247.

236. GATT Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *Status of Work in the Negotiating Group: Chairman's Report to the GNG* art. 5A.2.2c, MTN/GNG/NG11/W/76 (July 23, 1990), reprinted in GERVAIS, *supra* note 26, art. 1A.2.2c, at 248. The other grounds were strictly limited to a "declared national emergency," and "public interest concerning national security, or critical peril to life of the general public or body thereof," making an intended expansive definition of "exploitation of the patented invention by the government" very unlikely. See *id.* at 248–50.

237. TRIPS art. 31.

One American individual intimately involved in the TRIPS negotiations asserts that the phrase “public non-commercial use” was coined to reflect United States “government use” practice under 28 U.S.C. 1498.²³⁸ A last minute addition to the TRIPS Agreement supports this reading. The semiconductor industry, concerned that South Korea might consider its growing semiconductor sector a sector of “vital importance”²³⁹ and issue compulsory licenses for Intel chips if unable to obtain licenses for them, successfully lobbied for an exception to compulsory licensing under Article 31(c) for semiconductor technology *except for public non-commercial use*.²⁴⁰ The industry clearly intended to exclude semiconductor technology from compulsory licensing altogether except for situations of use by the government itself or a government contractor: “[i]f it’s a time of war and they need a chip for a missile, that’s one thing.”²⁴¹ Indeed, “[i]t was probably fitting for the US that of all the areas of technological knowledge that TRIPS locked up, chip-making, which lay at the heart of so many military and civilian technologies, was locked the tightest.”²⁴² By comparison, an expansive definition of public non-commercial use locks up nothing. To be clear, the term “public non-commercial use” was selected over any suggested “government use” term, and any definition must reflect that choice. However, the earlier TRIPS drafts, the negotiating history, and the eleventh-hour semiconductor exception suggests that public non-commercial use should be defined within close proximity to “government use.” This reading comports with the internal analysis of Article 31(b), providing a restriction reasonably

238. JACQUES GORLIN, AN ANALYSIS OF THE PHARMACEUTICAL RELATED PROVISIONS OF THE WTO-TRIPS INTELLECTUAL PROPERTY AGREEMENT 34 (1999). Under U.S. law, the government may use or manufacture patented inventions, with the patentee retaining the ability to sue for “reasonable and entire compensation.” 28 U.S.C. § 1498 (2006). The definition of government use includes use or manufacture by “a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government.” *Id.*

239. See TRIPS art. 8.

240. TRIPS art. 31(c) (“[T]he scope and duration of [compulsory licensing] shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a [non-competitive practice].” (emphasis added)); DRAHOS WITH BRAITHWAITE, *supra* note 7, at 147–49 (detailing the last-minute semiconductor amendment to TRIPS); *Implications of Intellectual Property Rights*, *supra* note 181, at 31 (noting that TRIPS included restrictions on “compulsory licenses, the treatment of innocent infringement, and the protection of designs” regarding semiconductor products, which had caused strong disagreement in earlier treaty negotiations).

241. DRAHOS WITH BRAITHWAITE, *supra* note 7, at 148–49 (noting that this last-minute amendment had paramount importance: the semiconductor industry’s “message must have clarified for US trade negotiators the last-minute changes they *absolutely had to have* in the draft TRIPS text and those they could give up” (emphasis added)); see also *Implications of Intellectual Property Rights*, *supra* note 181, at 31 (noting that semiconductor technology constituted a “main battlefield” at the time).

242. DRAHOS WITH BRAITHWAITE, *supra* note 7, at 149.

on par with the accompanying terms "national emergency" and "other circumstances of extreme urgency."

B. Government-Run Health Care and Non-Discrimination

Even with public non-commercial use closely cabined to government use, however, reading Article 31(b) in isolation suggests that *any* compulsory license issued for pharmaceutical drugs by a government health care program is valid. Indeed, Thailand issued its recent compulsory licenses under Section 51 of the Thai Patent Act, whereby "any ministry, bureau and department of government may, by themselves or through others" issue a compulsory license without engaging in prior negotiations.²⁴³ Such a statute is entirely consistent with TRIPS Article 31(b), because this situation falls neatly within the situation where a compulsory license does not require prior negotiation if the patent subject matter is used for a public non-commercial use.²⁴⁴ The Thai Patent Act would survive a *China*-like facial challenge.

If TRIPS only required compliance with Article 31(b) for compulsory licensing, a government-run universal, single-payer²⁴⁵ health care system could issue a compulsory license for any patented drug it desires to use. Such use appears "public" because the government distributes the drugs to its citizens through its health care program, and such use appears "non-commercial" because a single-payer system delivers its drugs to the public without charge.²⁴⁶ However, similar to how a default system of issuing compulsory licenses in instances of failed negotiations would be inconsistent with the exclusivity rights granted to IP owners under Article 28.1,²⁴⁷ a default or widespread practice of issuing compulsory licenses for pharmaceutical products begins to run afoul of the Article 27.1 prohibition on discrimination as to fields of technology, even if the Article 31(b) public non-commercial use restriction is satisfied.²⁴⁸ The

243. Patent Act B.E. 2522, § 51 (1979), *amended by* Patent Act (No.3) B.E. 2542 (1999) (Thai.), *reprinted in* THAI WHITE PAPER, *supra* note 2, at 30.

244. See TRIPS art. 31(b).

245. A health care provider in a single-payer governmental health care system, like Canada's health program or Medicare in the United States, "has only one entity to bill: the government." KAO-PING CHUA, AM. MED. STUDENT ASSOC., SINGLE PAYER 101, at 1 (2010).

246. See CARVALHO, *supra* note 191, ¶ 31.16 (noting, within a strongly restrictive interpretation of compulsory licensing, that "[t]he non-commercial nature of the use relates to the end-use of the invention, for example, the gratuitous distribution of medicaments to the poor"); CHUA, *supra* note 245, at 1; CIPIH REPORT, *supra* note 22, at 20 ("It seems indisputable that . . . the purchase of anti-retroviral medicines for distribution through public hospitals without commercial profit would come within scope of the term.").

247. See *supra* text accompanying notes 202–205.

248. See TRIPS art. 27.1 ("[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."). A Member issuing compulsory licenses for a broad range

Panel in *Canada—Patent Protection of Pharmaceutical Products* noted that it is an “acknowledged fact that the Article 31 exception for compulsory licences and government use is understood to be subject to the non-discrimination rule of Article 27.1.”²⁴⁹

The WTO dispute resolution system has long-recognized the doctrine of *de facto* discrimination in international trade law.²⁵⁰ Thus, a compulsory licensing regime that facially makes no reference to pharmaceutical products, but in effect substantially weakens IP rights in the pharmaceutical sector compared to another fields of technology, may still be discriminatory and violate TRIPS Article 27.1. Indeed, a WTO Panel has proved willing to address *de facto* discrimination as to field of technology under TRIPS Article 27.1 if a complainant can show “that the adverse effects [of a facially-neutral law] were limited to the pharmaceutical industry.”²⁵¹ In that particular case, however, the Panel ultimately did not issue a ruling because the complaining party did not satisfactorily raise a *prima facie* claim of *de facto* discrimination.²⁵²

A WTO panel, however, would likely be lenient when considering whether compulsory licenses issued were “necessary to protect public health,” and would likely be reluctant to invade a Member’s sovereignty to find discrimination unless a clear pattern of abuse was demonstrated.²⁵³ Panels should not find compulsory licenses discriminatory simply because certain fields of technology are more likely than others to be required to be utilized to address public health concerns under the restrictions specified in TRIPS Article 31.²⁵⁴ Thus, should a Member issue a wide array of compulsory licenses for HIV/AIDS medications to

of pharmaceutical products may also begin to discriminate as to the place of invention, since only a handful of developed countries have an innovative pharmaceutical industry, although this Note will focus on discrimination as to the field of technology.

249. *Canada—Patent Protection*, *supra* note 154, ¶ 7.91.

250. Where discrimination arises from explicitly differential treatment, it is *de jure* discrimination. Where discrimination occurs as a result of facially neutral treatment, it is *de facto* discrimination. *Id.* ¶ 7.94; *see also* CARVALHO, *supra* note 191, ¶ 27.8; Lothar Ehring, *De Facto Discrimination in World Trade Law: National and Most-Favoured-Nation Treatment—or Equal Treatment?*, 36 J. WORLD TRADE 921, 922–23 (2002). For example, a law applying varying tax rates to various types of alcoholic beverages, even if making no explicit distinction between imported and domestic beverages, may be *de facto* discriminatory if the majority of domestic drinks fall under low tax rates while a disproportionately high number of imported beverages fall under high tax rates. *See, e.g.*, Report of the Panel, *Japan—Customs Duties, Taxes and Labeling Practices on Imported Wines and Alcoholic Beverages*, ¶ 5.13, L/6216 (Nov. 10, 1987), GATT B.I.S.D. (34th Supp.) at 83 (1988).

251. *Canada—Patent Protection*, *supra* note 154, ¶ 7.105.

252. *Id.*

253. *See supra* text accompanying note 220.

254. *See Canada—Patent Protection*, *supra* note 154, ¶ 7.92 (“Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas.”).

combat a domestic epidemic, that exclusive use should be sufficiently tailored to avoid a finding of discrimination.²⁵⁵ For this reason, a panel would likely not find Thailand's HIV/AIDS compulsory licenses discriminatory. The single compulsory license for Plavix is also highly unlikely to trip the discrimination prohibition without a broader pattern of issuing compulsory licenses for pharmaceutical products. A series of compulsory licenses for Thailand's remaining wish list of essential drugs, perhaps building on the 2008 compulsory licenses for anticancer drugs, however, would appear to eviscerate the patentability of pharmaceutical drugs in Thailand in violation of Article 27.1, notwithstanding facial compliance with the Article 31 restrictions.²⁵⁶ Compulsory licensing for public non-commercial use need not address an emergency or "exceptional" situation, but neither is it a gateway for issuing compulsory licenses with near impunity.

CONCLUSION

In light of the evolving pharmaceutical marketplace, a developing internationally-recognized right to health care, and the proliferation of universal health care programs, this Note has suggested that expansive compulsory licensing may represent both a growing threat to future pharmaceutical R&D and a correspondingly tempting option to control health care costs. With the developing world assuming a larger role in the global pharmaceutical marketplace, compulsory licensing poses a tried-and-true method of keeping health care costs low despite the damaging impact it may have on the economic returns of pharmaceutical R&D. Further, with developed countries addressing health care budget problems and sometimes capping expenditures, compulsory licensing

255. See *id.* However, the Panel additionally noted:

[T]o the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than a frustration of purpose . . . in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers.

Id.

256. Because only a handful of developed countries have innovative pharmaceutical industries, see *supra* note 115 and accompanying text, such broad compulsory licensing practices also appear to discriminate with regard to country of origin. See TRIPS art. 27.1 ("[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention . . . and whether products are imported or locally produced."); *Canada-Patent Protection*, *supra* note 154, ¶ 7.92 (warning that governments may act discriminatorily when "succumb[ing] to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers").

may eventually pose as attractive an option for developed nations as it does for developing nations. Thus, this clarifying analysis of public non-commercial use, which represents the vanguard of compulsory licensing activity, may help to alleviate current uncertainty.

Under such an analysis, restraining the apparently open-ended plain language of public non-commercial use best balances the interests of users and producers of pharmaceutical products, and best comports with the language and context of TRIPS. Nearly limitless justification for compulsory licensing under the public non-commercial use restriction is incompatible with the harmonizing goals of TRIPS, particularly the principle of non-discrimination as to field of technology. Such a reading also renders superfluous the other restrictive Article 31(b) “national emergency” and “circumstances of extreme urgency” terms.

Adhering closely to the TRIPS text is also the best way to provide predictability and to balance WTO Members’ concerns about addressing public health care problems in light of a growing fundamental right to human health. WTO panels have respected national sovereignty by interfering only when there is explicit textual justification for doing so, providing leeway for nations to determine the necessity of utilizing compulsory licensing to address public health concerns. By clarifying permissible applications of public non-commercial use, pharmaceutical researchers can better anticipate market returns on research, nations can better identify acceptable methods of improving access to health care, and transaction costs for IP-related transactions will be lower due to increased harmonization. In addition, the current chill on compulsory licensing may thaw, permitting states to utilize compulsory licensing to address public health concerns in conclusively permissible circumstances.